

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. Food and Drug Administration**

FDA Emergency Operations Plan

Version 2.0

March 2014

OFFICE OF CRISIS MANAGEMENT

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A MESSAGE FROM THE COMMISSIONER

As part of the U.S. Food and Drug Administration's (FDA) mission to promote and protect the public health, the agency must be prepared to deal with a multitude of different types of emergencies that can involve, impact, or require the use of FDA-regulated products. The *FDA Emergency Operations Plan* (EOP) provides a framework for the agency to prepare for, prevent, mitigate, respond to, and recover from emergencies. Whether a natural disaster, foodborne illness outbreak, contaminated drug or biologic, faulty medical device, harmful pet food, influenza pandemic, or a national event such as the presidential inauguration, FDA must provide a coordinated response across field and headquarters organizational components.

This EOP describes FDA's overall role and responsibilities as well as those of its individual Centers and Offices relative to emergencies. It addresses the state of readiness required to monitor potential public health risks associated with FDA-regulated products. The EOP also outlines agency procedures for responding to and managing complex and life-threatening incidents that require extensive resources and coordination.

The revised FDA EOP contains several new elements. This plan:

- Incorporates agency organizational structure changes made since 2010 to more accurately reflect agency responsibilities, subject matter expertise, and mandates.
- Follows the guidance provided within Presidential Policy Directive 8 (PPD-8): *National Preparedness*, which provides for the Nation's framework, strategy, objectives, and requirements for emergency preparedness, response, and recovery.
- Ensures the agency's alignment with frameworks issued under PPD-8, including prevention, mitigation, response, and recovery.
- Eliminates the Crisis Management Annex. Relevant procedures of the Annex have been incorporated into the base plan to ensure a unified approach to all levels of incident scope and severity.

The FDA EOP is a living document that will be updated regularly to reflect organizational and policy changes, improvements in national incident management best practices and structures, and lessons learned from real-world incidents and exercises. For example, this revised plan features an updated and expanded annex to address processing mission assignment sub-taskings during disasters.

With FDA's unique combination of public health and regulatory response roles, there are few types of emergencies that would not call for some level of involvement on the part of FDA. Effective response hinges upon well-trained leaders and responders who have invested in response preparedness; therefore, I strongly urge agency staff to become familiar with this plan before the next emergency occurs. Individuals with a greater understanding of the agency's roles and responsibilities in an emergency or significant incident will be better prepared to serve the public.

Any questions regarding this FDA EOP can be directed to the Office of Crisis Management/Emergency Planning, Exercise, and Evaluation Staff (OCMEercisesandEvaluations@fda.hhs.gov).



Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

An electronic version of the FDA EOP and its annexes
can be found on the FDA.gov website at

<http://www.fda.gov/downloads/EmergencyPreparedness/EmergencyPreparedness/UCM230973.pdf>

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TABLE OF CONTENTS

A. Introduction.....	1
A.1 Mission	2
A.2 Purpose	3
A.3 Scope and Applicability	3
A.4 Planning Assumptions.....	4
A.5 Activation.....	5
A.5.1 Activation of EOP Annexes	5
A.6 Supersedence	6
B. Concept of Operations	7
B.1 Emergency Authorities	7
B.2 Emergency Operations Phases	8
B.2.1 Prevention, Protection, and Mitigation	8
B.2.1.1 Surveillance, Detection, and Alert.....	9
B.2.1.2 Consumer Product Protection.....	13
B.2.1.3 Medical Countermeasures	14
B.2.1.4 Increased Surveillance of FDA-Regulated Medical Products.....	14
B.2.2 Response	15
B.2.2.1 Gain and Maintain Situational Awareness	15
B.2.2.1.1 Alert and Notification.....	15
B.2.2.1.2 Assessment and Monitoring.....	16
B.2.2.2 Activation and Deployment of Resources and Capabilities	17
B.2.2.2.1 Authority to Change EOC Operational Levels	19
B.2.2.2.2 Conditions for Operational Level Change.....	19
B.2.2.3 Coordination of Response Actions	20
B.2.2.3.1 Initial and Ongoing Response Planning.....	21
B.2.2.3.2 FDA Field Response.....	21
B.2.2.3.3 FDA Headquarters Response.....	22
B.2.2.3.4 Mission Assignments in Support of State and Local Response	24
B.2.2.3.5 Medical Countermeasures: EUA and Expanded Access	24
B.2.2.4 Demobilization	25
B.2.3 Recovery	26
B.2.3.1 Evaluation of Response	27
C. Organization and Assignment of Responsibilities	29
C.1 Office of the Commissioner.....	31
C.1.1 Office of the Executive Secretariat.....	32
C.1.2 Office of the Chief Counsel	32
C.1.3 Office of Legislation.....	33
C.1.4 Office of Policy and Planning	33
C.1.4.1 Office of Policy	33
C.1.4.2 Office of Planning.....	33



C.1.5	Office of the Counselor to the Commissioner	33
C.1.5.1	Office of Crisis Management	33
C.1.5.1.1	Office of Emergency Operations.....	34
C.1.6	Office of External Affairs	35
C.1.6.1	Web and Digital Media Staff	35
C.1.6.2	Office of Communications.....	36
C.1.6.3	Consumer Health and Constituent Affairs	36
C.1.6.4	Office of Media Affairs.....	37
C.1.6.4.1	Media Relations Staff.....	37
C.1.7	Office of the Chief Scientist.....	37
C.1.7.1	Office of Counterterrorism and Emerging Threats.....	38
C.1.7.2	National Center for Toxicological Research	39
C.2	Office of Operations	40
C.2.1	Office of Business Services	40
C.2.2	Office of Finance, Budget, and Acquisition	40
C.2.2.1	Office of Budget	40
C.2.2.2	Office of Acquisitions and Grants Services.....	41
C.2.2.3	Office of Financial Operations	41
C.2.2.3.1	Office of Financial Management	41
C.2.2.3.2	Office of Financial Services	41
C.2.3	Office of Information Management.....	42
C.2.4	Office of Human Resources	43
C.2.5	Office of Facilities Engineering and Mission Support Services.....	43
C.2.6	Office of Security Operations	43
C.3	Office of Foods and Veterinary Medicine.....	44
C.3.1	Coordinated Outbreak Response and Evaluation Network	44
C.3.2	Center for Food Safety and Applied Nutrition	45
C.3.3	Center for Veterinary Medicine	46
C.4	Office of Medical Products and Tobacco	47
C.4.1	Office of Special Medical Programs.....	47
C.4.1.1	Office of Good Clinical Practice	48
C.4.1.2	Office of Combination Products	48
C.4.1.3	Office of Orphan Products Development.....	48
C.4.1.4	Office of Pediatric Therapeutics.....	49
C.4.1.5	Advisory Committee Oversight and Management Staff.....	49
C.4.2	Center for Drug Evaluation and Research	49
C.4.3	Center for Biologics Evaluation and Research	50
C.4.4	Center for Devices and Radiological Health	51
C.4.5	Center for Tobacco Products	51
C.5	Office of Global Regulatory Operations and Policy.....	53
C.5.1	Office of International Programs	53
C.5.2	Office of Regulatory Affairs	54
C.5.2.1	Deputy Associate Commissioner for Regulatory Affairs.....	55
C.5.2.1.1	Office of Communications and Quality Program Management	55

	C.5.2.1.2 Office of Policy and Risk Management.....	55
	C.5.2.1.3 Office of Partnerships	55
	C.5.2.2 Office of Resource Management	56
	C.5.2.3 Office of Criminal Investigations	56
	C.5.2.4 Office of Operations	57
	C.5.2.4.1 Office of Enforcement and Import Operations	57
	C.5.2.4.2 Office of Food and Feed Operations	58
	C.5.2.4.3 Office of Medical Products and Tobacco Operations	58
	C.5.2.4.4 Office of Regulatory Science	59
	C.5.2.4.5 ORA Regions and Districts	59
D.	Direction, Control, and Coordination	61
D.1	Field Incident Command	61
D.2	Headquarters Incident Coordination	63
D.2.1	Command Staff	64
D.2.1.1	Agency Incident Coordinator	64
D.2.1.2	Liaison Officers	65
D.2.1.3	Safety Officer	65
D.2.1.4	Public Information Officer.....	65
	D.2.1.4.1 FDA Joint Information Center	67
	D.2.1.4.2 Media Relations Group	67
	D.2.1.4.3 Web and Digital Media Group.....	67
	D.2.1.4.4 Stakeholder Outreach Group.....	68
	D.2.1.4.5 State and Local Officials Group	68
	D.2.1.4.6 Call Centers Liaison.....	68
	D.2.1.4.7 Congressional Liaison.....	68
	D.2.1.4.8 International Liaison to External Unified JIC.....	68
	D.2.1.4.9 Internal Communications Liaison.....	68
D.2.2	General Staff	69
D.2.2.1	Operations Section	69
	D.2.2.1.1 Operations Section Chief.....	69
	D.2.2.1.2 Divisions and Groups.....	69
	D.2.2.1.3 Center/Office Emergency Coordinators.....	70
D.2.2.2	Planning Section	70
	D.2.2.2.1 Planning Section Chief.....	70
	D.2.2.2.2 Units	71
	D.2.2.2.3 Technical Specialists	71
D.2.2.3	Logistics Section	72
	D.2.2.3.1 Units.....	72
	D.2.2.3.2 Technical Specialists	73
	D.2.2.3.3 EOC Facility Manager.....	73
D.2.2.4	Finance/Administration Section	73
	D.2.2.4.1 Units	73
D.2.3	Agency Executive Group.....	74
D.2.4	Multiagency Coordination.....	74
D.2.5	Multiagency Coordination Group for Foodborne Illness Outbreaks.....	75

E. Communications and Information Management.....	77
E.1 Intra-Agency Coordination	77
E.1.1 Emergency Alerts.....	77
E.1.2 Situation Reporting.....	78
E.1.3 Emergency Operations Network – Incident Management System	78
E.1.4 Government Emergency Telecommunications Service	79
E.2 Intergovernmental Coordination.....	80
E.2.1 Communicating with Federal Government Agencies.....	80
E.2.2 Communicating with State, Local, Tribal, and Territorial Governments.....	80
E.2.3 Communicating with Foreign Governments.....	81
E.3 Public Messaging	82
E.3.1 Coordination with Other Federal Agencies	82
E.3.2 Congress.....	83
F. Authorities and References	85
F.1 Statutes and Regulations	85
F.1.1 Federal Food, Drug, and Cosmetic Act.....	85
F.1.2 Public Health Service Act.....	87
F.1.3 Federal Anti-Tampering Act	87
F.1.4 Bioterrorism Act.....	87
F.1.5 Stafford Act.....	88
F.1.6 Public Readiness and Emergency Preparedness Act	88
F.1.7 Title 18 and Title 21 United States Code	88
F.1.8 Code of Federal Regulations Title 21	88
F.2 Presidential Directives.....	89
F.2.1 PPD-8, National Preparedness	89
F.2.2 National Preparedness Goal	89
F.2.3 National Preparedness System	89
F.2.4 National Planning Frameworks	89
F.2.5 HSPD-5, Management of Domestic Incidents	90
F.2.6 HSPD-7, Critical Infrastructure Identification, Prioritization, and Protection	90
F.2.7 HSPD-9, Defense of United States Agriculture and Food	90
F.2.8 HSPD-10, Biodefense for the 21st Century	90
F.2.9 HSPD-18, Medical Countermeasures Against Weapons of Mass Destruction	90
F.2.10 NSPD-51/HSPD-20, National Continuity Policy.....	90
F.2.11 HSPD-21, Public Health and Medical Preparedness.....	90
F.2.12 HSPD-22, Domestic Chemical Defense	90
F.3 National Strategies	91
F.3.1 National Strategy for the Physical Protection of Critical Infrastructures and Key Assets	91
F.3.2 National Strategy for Homeland Security.....	91
F.3.3 National Security Strategy.....	91
F.4 Federal Plans and Guidance.....	92
F.4.1 Comprehensive Preparedness Guide 101	92
F.4.2 National Incident Management System	92
F.4.3 National Infrastructure Protection Plan	92
F.4.4 National Preparedness Guidelines	92
F.4.5 National Response Framework.....	93
F.4.6 National Disaster Recovery Framework	93

F.5	HHS Plans.....	93
F.6	FDA Supporting Documentation	94
F.6.1	Center/Office Emergency Plans and Procedures	94
F.6.2	SOP for FDA Headquarters Building Closures and Dismissal of Employees.....	95
F.6.3	Center/Office COOP Plans	95
G.	Plan Management	97
G.1	Coordination	97
G.2	Maintenance.....	97
G.3	Promulgation	97
G.4	Standards for Supporting Documentation	97
G.5	Training and Exercises.....	98
G.6	Implementation.....	98
Appendix A: FDA Support for the Emergency Support Function Annexes to the National Response Framework..... App A-1		
A.1	ESF #8 – Public Health and Medical Services.....	App A-1
A.2	ESF #10 – Oil and Hazardous Materials Response	App A-4
A.3	ESF #11 – Agriculture and Natural Resources	App A-5
Appendix B: FDA Support for the Incident Annexes to the NRF App B-1		
B.1	Biological Incident Annex	App B-1
B.2	Catastrophic Incident Annex	App B-2
B.3	Food and Agriculture Incident Annex	App B-3
B.4	Nuclear/Radiological Incident Annex	App B-5
B.5	Terrorism Incident Law Enforcement and Investigation Annex	App B-6
Appendix C: Processing Mission Assignment Sub-Taskings App C-1		
C.1	Purpose	App C-1
C.2	Assumptions.....	App C-1
C.3	Scope	App C-1
C.4	Procedure.....	App C-2
C.4.1	Processing Action Request Form	App C-2
C.4.1.1	FDA/State Coordination.....	App C-2
C.4.1.1	Initial FDA Internal Coordination (Field and Headquarters).....	App C-3
C.4.2	Processing a Mission Assignment Sub-Task.....	App C-3
C.4.2.1	FDA/FEMA/HHS Coordination.....	App C-3
C.4.2.2	FDA Internal Coordination	App C-4
C.4.2.3	MA Monitoring and Closeout	App C-4
Attachment C-1: FDA Pre-Scripted Mission Assignments..... App C-1-1		
Attachment C-2: ARF for FDA Retail Food Establishment Inspections Sample.... App C-2-1		
Attachment C-3: MA Form Based On Completed ARF Sample..... App C-3-1		
Attachment C-4: Stafford Act Mission Sub-Tasking Based on MA Form Sample . App C-4-1		
Appendix D: Characteristics of Potential Foodborne Agents..... App D-1		
Appendix E: Chemical Agents – Background Information App E-1		
E.1	General Information	App E-1
E.2	Classes of Chemical Warfare Agents	App E-1
E.3	Nerve Agent Exposure Versus Nerve Agent Intoxication	App E-2

E.4	Chemical Agent Characteristics	App E-3
E.5	List of Additional Chemical Agents.....	App E-4
Appendix F: Biological Agents – Background Information		App F-1
F.1	General Information	App F-1
F.2	Classes of Biological Warfare Agents.....	App F-1
F.3	Epidemiologic Clues That May Signal a Covert Bioterrorism Attack	App F-2
F.4	Bioterrorism Agents/Diseases By Category	App F-3
Appendix G: Oversight of Select Agents and Toxins by HHS/CDC and USDA/Animal and Plant Health Inspection Service		App G-1
G.1	HHS Select Agents and Toxins.....	App G-1
G.2	Overlap Select Agents and Toxins.....	App G-1
G.3	USDA Select Agents and Toxins	App G-2
G.4	USDA Plant Protection and Quarantine Select Agents and Toxins.....	App G-3
Appendix H: Domestic and International Traceback/Traceforward.....		App H-1
H.1	Domestic	App H-1
H.2	International.....	App H-1
Appendix I: Memorandum of Understanding.....		App I-1
Appendix J: Forms and Templates.....		App J-1
Appendix K: Glossary of Terms.....		App K-1
Appendix L: List of Acronyms and Abbreviations.....		App L-1

Nuclear/Radiological Annex to the FDA Emergency Operations Plan

A. Introduction.....		Nuc/Rad Annex-1
A.1	Mission	Nuc/Rad Annex-1
A.2	Purpose	Nuc/Rad Annex-1
A.3	Scope and Applicability	Nuc/Rad Annex-2
A.4	Planning Assumptions.....	Nuc/Rad Annex-2
A.5	Activation.....	Nuc/Rad Annex-2
A.6	Supersedence	Nuc/Rad Annex-2
B. Concept of Operations		Nuc/Rad Annex-3
B.1	Emergency Authorities	Nuc/Rad Annex-3
B.2	Emergency Operations Phases	Nuc/Rad Annex-3
B.2.1	Prevention, Protection, and Mitigation	Nuc/Rad Annex-3
B.2.1.1	Surveillance and Detection	Nuc/Rad Annex-4
B.2.1.1.1	Winchester Engineering and Analytical Center	Nuc/Rad Annex-4
B.2.2	Response	Nuc/Rad Annex-4
B.2.2.1	Gain and Maintain Situational Awareness	Nuc/Rad Annex-4
B.2.2.1.1	Alert and Notification.....	Nuc/Rad Annex-4
B.2.2.1.2	Assessment and Monitoring.....	Nuc/Rad Annex-4
B.2.2.2	Medical Countermeasures	Nuc/Rad Annex-4
B.2.2.3	Activation and Deployment of Resources and Capabilities	Nuc/Rad Annex-5
B.2.2.4	Coordination of Response Actions	Nuc/Rad Annex-5
B.2.2.4.1	Exposure Determination Information	Nuc/Rad Annex-5

B.2.3	Recovery	Nuc/Rad Annex-6
C.	Organization and Assignment of Responsibilities	Nuc/Rad Annex-7
C.1	Office of the Commissioner	Nuc/Rad Annex-7
C.1.1	Office of the Counselor to the Commissioner	Nuc/Rad Annex-7
C.1.1.1	Office of Crisis Management	Nuc/Rad Annex-7
C.1.2	Office of Operations	Nuc/Rad Annex-8
C.1.2.1	Employee Safety and Environmental Management Staff	Nuc/Rad Annex-8
C.1.3	Office of Chief Scientist.....	Nuc/Rad Annex-8
C.1.3.1	Office of Counterterrorism and Emerging Threats.....	Nuc/Rad Annex-8
C.2	Office of Foods and Veterinary Medicine	Nuc/Rad Annex-9
C.2.1	Center for Food Safety and Applied Nutrition	Nuc/Rad Annex-9
C.3	Office of Global Regulatory Operations and Policy.....	Nuc/Rad Annex-10
C.3.1	Office of Regulatory Affairs	Nuc/Rad Annex-10
C.3.1.1	Regional Radiological Health Representatives	Nuc/Rad Annex-10
D.	Direction, Control, and Coordination	Nuc/Rad Annex-11
D.1	Field Incident Command	Nuc/Rad Annex-11
D.2	Headquarters Incident Coordination	Nuc/Rad Annex-11
D.2.1	Command Staff	Nuc/Rad Annex-12
D.2.1.1	Radiological-Specific Liaisons	Nuc/Rad Annex-12
D.2.2	General Staff	Nuc/Rad Annex-12
D.2.2.1	Operations Section	Nuc/Rad Annex-12
D.2.1.2	Drug Group	Nuc/Rad Annex-13
D.2.1.2.1	Expired Drugs Team	Nuc/Rad Annex-13
D.2.1.2.2	Drug Shortage Team	Nuc/Rad Annex-13
D.2.1.2.3	Adverse Drug Events Team.....	Nuc/Rad Annex-13
D.2.1.3	Biologics Group.....	Nuc/Rad Annex-13
D.2.1.4	Medical Device Group.....	Nuc/Rad Annex-13
D.2.1.4.1	In-Vitro Diagnostics Team.....	Nuc/Rad Annex-13
D.2.1.4.2	Personal Protective Equipment and Other Devices Team	Nuc/Rad Annex-14
D.2.1.4.3	Shortage Team	Nuc/Rad Annex-14
D.2.1.5	Food/Feed Safety Group	Nuc/Rad Annex-14
D.2.2.2	Planning Section	Nuc/Rad Annex-15
D.2.2.2.1	Radiological Emergency Response Unit	Nuc/Rad Annex-15
D.2.2.2.2	Technical Specialists	Nuc/Rad Annex-15
D.2.2.2.3	Employee Health Specialist	Nuc/Rad Annex-15
E.	Communications and Information Management.....	Nuc/Rad Annex-16
E.1	Emergency Alerts.....	Nuc/Rad Annex-16
E.2	External Information Sharing.....	Nuc/Rad Annex-17
E.2.1	Information Sharing Process.....	Nuc/Rad Annex-17

F. Authorities and References	Nuc/Rad Annex-19
F.1 Code of Federal Regulations	Nuc/Rad Annex-19
F.2 Federal Plans and Guidance.....	Nuc/Rad Annex-19
F.3 FDA Supporting Documentation	Nuc/Rad Annex-20
F.3.1 WEAC Radiation Safety Manual	Nuc/Rad Annex-20
F.3.2 CFSAN Radiological Emergency Response Plan	Nuc/Rad Annex-20
F.3.3 FDA Food Protective Guidance	Nuc/Rad Annex-20
Appendix A: Winchester Engineering Analytical Center.....	Nuc/Rad Annex-21
Appendix B: Activation/Notification of the Advisory Team for Nuclear/Radiological Emergencies	Nuc/Rad Annex-23
Appendix C: Protective Actions.....	Nuc/Rad Annex-27
Appendix D: Memorandum of Understanding	Nuc/Rad Annex-29
Appendix E: FDA Responsibilities During Radiological Incidents.....	Nuc/Rad Annex-31

Pandemic Influenza Annex to the FDA Emergency Operations Plan

A. Introduction.....	PI Annex-1
A.1 Mission	PI Annex-1
A.2 Purpose	PI Annex-1
A.3 Scope and Applicability	PI Annex-2
A.4 Planning Assumptions.....	PI Annex-3
A.5 Activation.....	PI Annex-4
A.6 Supersedence	PI Annex-4
B. Concept of Operations	PI Annex-5
B.1 Emergency Authorities	PI Annex-5
B.2 Emergency Operations Phases	PI Annex-5
B.2.1 Prevention and Protection.....	PI Annex-5
B.2.1.1 Surveillance and Detection	PI Annex-5
B.2.1.2 Consumer Product Protection.....	PI Annex-5
B.2.1.3 Medical Countermeasures	PI Annex-6
B.2.1.4 Increased Surveillance of FDA-Regulated Pandemic Influenza Medical Products	PI Annex-6
B.2.2 Response	PI Annex-6
B.2.2.1 Gain and Maintain Situational Awareness	PI Annex-6
B.2.2.1.1 Alert and Notification.....	PI Annex-6
B.2.2.1.2 Administrative Alert and Notification	PI Annex-6
B.2.2.2 Coordination of Response Actions	PI Annex-6
B.2.2.2.1 FDA Headquarters Response.....	PI Annex-6
B.2.2.2.2 Medical Countermeasures Expanded Access and EUA.....	PI Annex-7
B.2.2.3 Demobilization	PI Annex-7
B.2.3 Recovery	PI Annex-7

C. Organization and Assignment of Responsibilities PI Annex-8

C.1	Office of the Commissioner.....	PI Annex-9
C.1.1	Office of the Chief Counsel	PI Annex-10
C.1.2	Office of Legislation.....	PI Annex-10
C.1.3	Office of Policy and Planning	PI Annex-10
C.1.4	Office of the Counselor to the Commissioner	PI Annex-10
C.1.4.1	Office of Crisis Management	PI Annex-11
C.1.5	Office of External Affairs	PI Annex-12
C.1.5.1	Web and Digital Media Staff	PI Annex-13
C.1.5.2	Office of Communications.....	PI Annex-13
C.1.5.3	Office of Media Affairs/Media Relations.....	PI Annex-13
C.1.5.4	Office of Health and Constituent Affairs.....	PI Annex-14
C.2	Office of the Chief Scientist.....	PI Annex-15
C.2.1	Office of Counterterrorism and Emerging Threats.....	PI Annex-15
C.3	Office of Operations	PI Annex-16
C.3.1	Office of Finance, Budget, and Acquisition	PI Annex-18
C.3.1.1	Office of Budget	PI Annex-18
C.3.1.2	Office of Acquisitions and Grants Services.....	PI Annex-19
C.3.1.3	Office of Financial Operations	PI Annex-20
C.3.1.3.1	Office of Financial Management	PI Annex-20
C.3.2	Office of Information Management.....	PI Annex-20
C.4	Office of Foods and Veterinary Medicine	PI Annex-24
C.4.1	Coordinated Outbreak Response and Evaluation	PI Annex-24
C.4.2	Center for Food Safety and Applied Nutrition	PI Annex-24
C.4.3	Center for Veterinary Medicine	PI Annex-26
C.5	Office of Medical Products and Tobacco	PI Annex-27
C.5.1	Office of Special Medical Programs.....	PI Annex-27
C.5.1.1	Office of Combination Products	PI Annex-27
C.5.2	Center for Drug Evaluation and Research	PI Annex-27
C.4.3	Center for Biologics Evaluation and Research	PI Annex-29
C.5.4	Center for Devices and Radiological Health	PI Annex-31
C.6	Office of Global Regulatory Operations and Policy.....	PI Annex-33
C.6.1	Office of International Programs	PI Annex-33
C.6.2	Office of Regulatory Affairs	PI Annex-34
C.6.2.1	Office of Regulatory Affairs Laboratories.....	PI Annex-35

D. Direction, Control, and Coordination PI Annex-36

D.1	Command Staff	PI Annex-37
D.1.1	Pandemic Influenza-Specific Liaisons	PI Annex-37
D.1.2	Legal Advisor	PI Annex-37
D.1.2.1	Legal Group	PI Annex-37
D.2	General Staff	PI Annex-37
D.2.1	Operations Section.....	PI Annex-37



D.2.1.1	Drug Group	PI Annex-38
D.2.1.1.1	Antiviral Team	PI Annex-38
D.2.1.1.2	Expired Drugs Team	PI Annex-38
D.2.1.1.3	Drug Shortage Team	PI Annex-38
D.2.1.1.4	Adverse Drug Events Team.....	PI Annex-38
D.2.1.2	Biologics Group.....	PI Annex-38
D.2.1.2.1	Vaccine Team	PI Annex-38
D.2.1.2.2	Blood Team.....	PI Annex-39
D.2.1.3	Medical Device Group.....	PI Annex-39
D.2.1.3.1	In-Vitro Diagnostics Team.....	PI Annex-39
D.2.1.3.2	Personal Protective Equipment and Other Devices Team	PI Annex-39
D.2.1.3.3	Shortage Team	PI Annex-40
D.2.2	Logistics Section	PI Annex-40
D.2.2.1	Employee Health Advisor.....	PI Annex-40
E.	Communications and Information Management.....	PI Annex-41
F.	Authorities and References	PI Annex-42
F.1	National Strategies	PI Annex-42
F.2	Federal Plans and Guidance.....	PI Annex-42
F.3	FDA Supporting Documentation	PI Annex-43
Appendix A: Protection of Workers: Guidance on Preparing the Workplace and Workers for an Influenza Pandemic		PI Annex-45

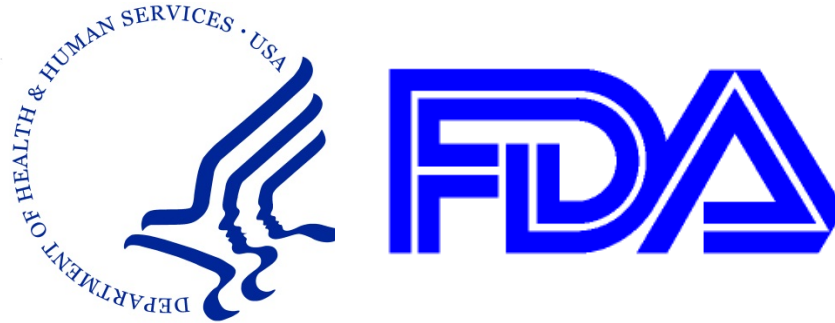
LIST OF FIGURES

Figure B-1. FDA Emergency Response Elements	15
Figure B-2. FDA Emergency Response Decision Tree	17
Figure C-1. FDA Organizational Chart.....	30
Figure C-2. FDA OC Organizational Chart	31
Figure C-3. FDA Regions and Districts	59
Figure D-1. FDA Field Incident Management Team	62
Figure D-2. FDA Headquarters Incident Management Group	63
Figure D-3. FDA's Joint Information System.....	66
Figure D-4. FDA Joint Information Center Possible Structure	66
Figure D-5. Operations Section Organizational Elements	69
Figure D-6. Planning Section Organizational Elements.....	70
Figure D-7. Logistics Section Organizational Elements.....	72
Figure D-8. Finance/Administration Section Organizational Elements	73
Figure D-9. MAC-FIO Unified Coordination for Foodborne Illness Outbreaks	75
Figure C-1. Process Overview	App C-2
Figure D-1. Notional FDA IMG for a Nuclear/Radiological Event	Nuc/Rad Annex-11
Figure D-2. Notional Operations Section Organizational Elements.....	Nuc/Rad Annex-12
Figure E-1. Emergency Alert Reporting Pathways	Nuc/Rad Annex-16
Figure E-2. Notional FDA Food and Agricultural Nuclear/Radiological Incident Communications Links.....	Nuc/Rad Annex-17
Figure A-1. Continuum of Pandemic Phases.....	PI Annex-2
Figure D-1. Possible Pandemic Influenza IMG Structure	PI Annex-36

LIST OF TABLES

Table B-1. Surveillance and Detection Systems Utilized by FDA.....	10
Table B-2. FDA Incident Levels and EOC Operation Levels	18
Table A-1. ESF Roles Aligned to Core Capabilities.....	Nuc/Rad Annex-2
Table E-1. FDA Communication Links by IMG Position and Center/Office.....	Nuc/Rad Annex-18
Table C-1. Principal Radionuclides and Corresponding DILs.....	Nuc/Rad Annex-27
Table E-1. FDA Responsibilities for Radiological Incidents.....	Nuc/Rad Annex-31

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**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. Food and Drug Administration**

FDA Emergency Operations Plan

Version 2.0

March 2014

OFFICE OF CRISIS MANAGEMENT

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A. INTRODUCTION

For purposes of this plan and its supporting annexes:

An **incident** is defined as: An occurrence or event, natural or manmade, that requires the attention of the U.S. Food and Drug Administration (FDA). At the incident level, FDA is aware of the circumstances, is monitoring and assessing the situation, and is determining whether it has regulatory authority over the incident. FDA may initiate response operations as described in this plan as appropriate. Any incident may evolve into an emergency.

An **emergency** is defined as: An unforeseen occurrence or a combination of circumstances that poses a significant risk to public health and that involves the safety, efficacy, and security of human and veterinary medicines, biological products, medical devices, our Nation's food supply, cosmetics, products that emit radiation, and tobacco products that call for immediate actions by FDA staff.

Since each emergency situation is unpredictable and dynamic, and any incident has the potential to escalate into an emergency, this plan will use the terms "incident" and "emergency" interchangeably.

Emergencies and disasters, whether natural or manmade, accidental or intentional, have the potential to cause adverse health and safety effects for large segments of the human and animal populations. In order to mitigate the consequences of such incidents, FDA must possess the resources and capabilities necessary to prevent, prepare for, protect against, and rapidly and effectively respond to and recover from all hazards. A planned and coordinated approach to emergency operations by FDA organizational components in support of Federal, State, local, tribal, and territorial (SLTT) government, with assistance when appropriate from foreign counterparts and international partners, can save lives and ensure that critical public health and medical needs are met.

This *FDA Emergency Operations Plan (EOP)* and its annexes are an all-discipline, all-hazards plan that establishes a single, comprehensive framework for the FDA's management of incidents. It provides the measures, operating structures, roles and responsibilities, and mechanisms for direction and coordination of FDA resources before, during, and after disease outbreaks, terrorist attacks and other criminal acts, natural disasters, and any other incidents associated with FDA-regulated products that pose a risk to human or animal health.

This FDA EOP is compatible with the scalable, flexible, and adaptable Federal Government emergency coordinating structures of the *National Response Framework (NRF)*; is consistent with the concepts, principles, and terminology of the *National Incident Management System (NIMS)*;¹ and it fulfills the requirements of:

- Post-Katrina Emergency Management Reform Act of 2006 (Public Law [P.L.] 109-295)
- Presidential Policy Directive 8 (PPD-8): *National Preparedness*
- National Preparedness Goal (NPG)
- National Preparedness System
- National Planning Frameworks
- Interagency Operational Plans
- Federal Emergency Management Agency's (FEMA) Comprehensive Preparedness Guide (CPG 101): *Developing and Maintaining State, Territorial, Tribal, and Local Government Emergency Plans*, March 2009
- U.S. Department of Homeland Security's (DHS) *The Integrated Planning System*, January 2009

This FDA EOP is to be used to guide FDA in conducting response operations for all types of incidents.

¹ For more information on the NRF and NIMS, refer to the "Authorities and References" section of this EOP.

A.1 MISSION

FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary medicines, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation and by regulating tobacco products. Additionally, FDA advances public health by helping to speed innovations that make foods safer and medical products more effective, safer, and more affordable and by helping the public get the accurate scientific information it needs to use medical products and foods to improve their health.

FDA must continue to meet its mission during emergency and disaster situations, under adverse conditions, and/or from alternate locations as needed. In addition to day-to-day activities, FDA activities may expand to include performance of specific incident-related functions, such as:

- Assisting and supporting the U.S. Department of Health and Human Services (HHS) in public health- and medical-related efforts to prevent, respond, mitigate, and recover from an incident.
- Conducting inspections and investigations and assessing damage to FDA-regulated industry in impacted areas.
- Coordinating the tracing (forward and backward) of the distribution of any potentially contaminated FDA-regulated products and initiating seizures or recalls as appropriate.
- Collecting and analyzing product samples.
- Providing technical assistance or subject matter expertise related to food and feed, human and animal drugs, medical devices, biologics, radiation-emitting devices, and tobacco products.
- Conducting assessments of food retail establishments in impacted areas.
- Conducting assessments of tobacco product retail establishments nationwide.
- Conducting reviews of all adverse event reports related to FDA-regulated products.
- Assisting with surveillance efforts to determine product integrity of foods, pharmaceuticals, medical supplies, equipment, and tobacco products.
- Authorizing the use of an unapproved medical product (drug, biologic, and device) or the unapproved use of an approved medical product (i.e., emergency use authorization [EUA]).
- Issuing safety alerts, health information advisories, warnings, and advice and guidance to consumers and industry.
- Requiring product manufacturers to make safety-related changes to prescribing information or labeling.
- Detaining or removing contaminated or unfit merchandise from the market and/or restricting those marketing it.

A.2 PURPOSE

The purpose of the FDA EOP is to provide for a coordinated and consistent agency approach to preparing for, preventing, protecting against, mitigating, responding to, and recovering from incidents involving or impacting FDA-regulated products.

To accomplish this, the FDA EOP:

- Serves as the single, overarching FDA-wide operational plan to address the full spectrum of natural and technological hazards and terrorist threats and the “umbrella plan” into which all supporting agency emergency plans, procedural documents, and other guidance integrate.
- Defines the FDA emergency operating structure and assigns essential tasks to all FDA organizational components involved in prevention, protection, mitigation, response, and recovery efforts.
- Provides mechanisms for vertical and horizontal command, control, coordination, and communications.
- Integrates FDA emergency response operations into the Federal coordinating structure and ensures consistency with nationally recognized incident management policy and guidance.

A.3 SCOPE AND APPLICABILITY

The FDA EOP covers the full range of complex and constantly changing requirements in anticipation of or in response to all “incidents” that FDA manages or participates in, including the following:

- Complaints, adverse events, recalls, or unintentional contamination involving FDA-regulated products that present a threat of serious adverse health consequences or death to humans or animals.
- Natural disasters (e.g., hurricanes, tornadoes, severe storms, floods, fires, earthquakes, volcanic eruptions, tsunamis, landslides).
- Naturally occurring disease and foodborne illness outbreaks, epidemics, and pandemics.
- Manmade accidents, such as hazardous materials releases or spills; air, land, or water contamination; and utility outages.
- Terrorist or criminal acts, including the threat or intentional use of chemical, biological, radiological, nuclear, or high-yield explosive (CBRNE) weapons against human or animal populations or FDA-regulated products.

The FDA EOP establishes intra- and interagency mechanisms for FDA involvement in domestic and international incident management operations. These mechanisms include coordinating structures and processes for incidents requiring agency support for consumer protection and to other Federal Agencies; States and territories, tribal nations, and local governments; foreign governments; and international organizations. It is applicable to all FDA headquarters and field organizational components that may be required to provide assistance or conduct emergency operations in the context of actual or potential incidents. In these cases, FDA may use the Incident Command System (ICS) to facilitate command and coordination.

A.4 PLANNING ASSUMPTIONS

The FDA EOP is based on the following planning assumptions:

- Incidents, including large-scale emergencies and major disasters, will require full coordination of FDA operations and resources, and may:
 - Occur at any time with little or no warning in the context of a general or specific threat or hazard.
 - Involve one or more FDA organizational component(s) and span a single or multiple region(s).
 - Require significant information sharing, resource coordination, and/or assistance across FDA organizational components, Federal and SLTT agencies, the private sector, and foreign governments.
 - Result in numerous casualties, fatalities, and displaced people; property loss; significant damage to the environment; and disruption of economy and normal life-support systems, essential public services, and critical infrastructures.
 - Require extremely short-notice FDA response times and prolonged, sustained recovery operations and support activities.
- All FDA emergency-related activities will be initiated and conducted in accordance with the principles, concepts, and terminology established within NIMS.
- Regardless of incident characteristics or requirements, FDA continues to be responsible for consumer products under its jurisdiction while coordinating response operations with other interagency public health and medical partners.
- An emergency or disaster that overwhelms the capabilities of State and local governments may require FDA and/or other Federal Agencies to assist in meeting public health and safety needs. FDA assets will supplement the response, as directed or requested, when an incident affects an FDA-regulated product or requires the provision of subject matter expertise or use of specific medical countermeasures. As such, FDA will participate in an Incident Command or Unified Command (UC) system to manage multi-agency emergencies.
- Contamination of the Nation's human and animal food or medical products supply may initially be indistinguishable from a naturally occurring event. Moreover, depending upon the particular agent and associated signs or symptoms, several days or weeks could pass before authorities suspect terrorism may be the cause.
- Response to a chemical, biological, radiological, or nuclear (CBRN) incident suspected of being deliberate in origin or a terrorist act requires consideration of special law enforcement and homeland security requirements as well as international legal obligations and requirements.
- The combined expertise and capabilities of government at all levels, industry, and nongovernmental organizations (NGOs) will be required to respond to incidents of catastrophic proportions. During such periods, FDA will provide emergency support as directed by the Commissioner, the Secretary of HHS, and/or the Secretary of Homeland Security through the coordinating mechanisms established within the NRF and *National Disaster Recovery Framework* (NDRF).
- Supporting documentation (e.g., standard operating procedures [SOPs], operations and procedural manuals, field guidance) has been developed and made available to designated FDA emergency staff to provide detailed instructions during performance of specific functions or incident-related actions.

- As part of its Emergency Support Function (ESF) #8 functions, FDA can provide SLTT agencies with activities related to regulated product support. For example, FDA can provide assistance to State and local agencies in ensuring the safety of food products at retail food establishments and drug and medical products in pharmacies.
- To ensure the capability to implement the FDA EOP, each FDA headquarters and field organizational component tasked with emergency roles and responsibilities, as identified in this EOP basic plan or any of its annexes, may develop and maintain individual emergency plans and procedures that identify the critical and time-sensitive missions, functions, assignments, and processes to be performed during all hazards. These documents shall be consistent with this EOP and be available to all FDA personnel.

A.5 ACTIVATION

While many parts of this EOP may be used routinely to manage FDA's emergency operations, the full plan will be activated when certain events occur such as, but not limited to, the following:²

- A determination has been made by the Commissioner of Food and Drugs (the Commissioner) or other FDA senior official(s) as delegated by the Commissioner that FDA emergency actions are warranted to prevent, prepare for, protect against, mitigate, respond to, or recover from a threat or hazard.
- The Secretary of HHS (the Secretary) has directed FDA to provide emergency support to maintain the safety, efficacy, and security of drugs, biologics, medical devices, radiation-emitting devices, the food supply, or cosmetics.
- The Secretary has directed FDA to provide emergency support to protect the public health in the event of tobacco product adulteration.
- The Secretary of Homeland Security has raised the National Terrorism Advisory System (NTAS) alert level.
- The President has declared that an emergency or a major disaster exists within an affected State or States as defined in the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), P.L. 100-707, as amended, and that NRF coordinating mechanisms, in whole or in part, have been activated.
- The President has declared a national emergency exists under the National Emergencies Act, 50 United States Code (U.S.C.) 1601-1651, in the event that the Nation is threatened by crisis, exigency, or emergency circumstances (other than natural disasters, war, or near-war situations).
- The Secretary of HHS may, under Section 319 of the Public Health Service Act (PHSA) determine that (a) a disease or disorder presents a public health emergency, or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

A.5.1 Activation of EOP Annexes

A decision on whether an EOP annex is to be implemented in response to an incident is made by the Office of Crisis Management (OCM) Director, in consultation with the Counselor to the Commissioner and senior officials of the Center(s) involved, or in a meeting requested by the Commissioner, a Center Director, the Associate Commissioner for Regulatory Affairs (ACRA), the Director of OCM, or some

² Regional Food and Drug Directors, District Directors, and Center/Office Directors may activate their individual organizational component's EOP without activation of the FDA EOP.



other top official specifically to discuss a particular incident or problem. If an annex(es) is to be activated, the OCM Director will notify the involved FDA parties (through electronic mail, if available).

A.6 SUPERSEDITION

This FDA EOP (version 2.0) supersedes the FDA EOP (version 1.2) and its annexes, dated August 2010.

B. CONCEPT OF OPERATIONS

The scope of FDA emergency operations is as wide as the array of products the agency regulates. FDA actions impact the Nation's quality of life on a daily basis through its regulation of food, drugs, medical devices, radiation-emitting products, biologics, veterinary drugs, and tobacco products. For this reason, FDA's successful and efficient handling of emergencies and disasters is especially important in fulfilling its mission to maintain not only the public's health, but also its trust and confidence. The following concept of operations (CONOPS) describes the principal authorities' governing agency emergency functions and the phases within which FDA conducts incident-related operations.³

B.1 EMERGENCY AUTHORITIES

Statutory authorities relevant to FDA emergency preparedness and response are described below under the general categories of safety and medical countermeasures. In addition, certain FDA regulations in Title 21 of the Code of Federal Regulations (CFR) may apply in an emergency situation.

- Safety of FDA-regulated products:
 - Under the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act), 21 U.S.C. 301 *et seq.*, as amended, FDA regulates the safety of, among other things, food, including dietary supplements, infant formula, and animal feed; human and animal drugs; medical devices; electronic products emitting radiation; and tobacco products.
 - Under PHSA, 42 U.S.C. 262, FDA will only approve a biologics license application upon a demonstration that the biological product is safe, pure, and potent. In addition, under PHSA, 42 U.S.C. 264, FDA may issue and enforce regulations necessary to prevent the spread of communicable disease.
- Medical countermeasures:
 - Under the FD&C Act, FDA generally approves drugs and devices that have been shown to be safe and effective. Under PHSA, FDA licenses biological products based upon a determination that they are safe, pure, and potent.
 - Section 561 of the FD&C Act (Expanded Access to Unapproved Therapies and Diagnostics) allows FDA to permit the treatment of a patient with an investigational medical countermeasure under certain circumstances, even though the safety and effectiveness of the drug have not been fully established.
 - Section 564 of the FD&C Act, as amended by the Project BioShield Act of 2004, allows FDA to authorize the emergency use of drug(s), device(s), or biological product(s) during a declared emergency under certain circumstances.
 - The Public Readiness and Emergency Preparedness Act of 2005 (PREP Act) (42 U.S.C. 247d-6d) concerns, among other things, liability protection for the use of designated medical countermeasures.

³ For detailed information on the actions performed during specific incidents, refer to the FDA EOP Incident Annexes.

B.2 EMERGENCY OPERATIONS PHASES

The following phases comprise the entire spectrum of FDA emergency operations: ***Prevention***, ***Protection***, ***Mitigation***, ***Response***, and ***Recovery***. Although emergency operations may involve each of these phases over the course of any multitude of incidents, the nature and severity of an event and the FDA organizational component(s) responding will determine the specific order, actions, and responsible parties required for each.⁴

B.2.1 Prevention, Protection, and Mitigation

FDA closely integrates the prevention, protection, and mitigation phases. These three phases are mission areas under the NPG and defined as follows:

- ***Prevention*** includes those capabilities necessary to avoid, prevent, or stop a threatened or actual act of terrorism. It is focused on ensuring we are optimally prepared to prevent an imminent attack within the United States.
- ***Protection*** includes capabilities to safeguard the homeland against acts of terrorism and manmade or natural disasters. It is focused on actions to protect the citizens, residents, visitors, and critical assets, systems, and networks against the greatest risks to our Nation in a manner that allows our interests, aspirations, and way of life to thrive. We will create conditions for a safer, more secure, and more resilient Nation by enhancing protection through cooperation and collaboration with all sectors of society.
- ***Mitigation*** includes those capabilities necessary to reduce loss of life and property by lessening the impact of disasters. It is focused on the premise that individuals, the private sector, communities, critical infrastructure, and the Nation as a whole are made more resilient when the consequences and impacts, the duration, and the financial and human costs to respond and recover from adverse incidents are all reduced.

The “prevention, protection, and mitigation” phase of FDA emergency operations includes those actions taken to avoid an incident or intervene to stop an incident from occurring, or to mitigate its effects on FDA-regulated products and the community, during periods of increased risk or heightened threat conditions.⁵ It involves immediate steps to protect consumers; ensure the safety and defense of food and animal feed, medical products (e.g., blood donations and diagnostic devices), cosmetics, field operations, and toxicological research; and apply intelligence and other information to a range of directed counter-measures. Upon preliminary determination of an incident, FDA conducts the following preventive/protective/mitigation measures:

- Conducting scientific ***vulnerability assessments*** of different categories of food to determine the most serious risks of intentional contamination.
- Providing ***preventive training tools*** to Government, industry, and other stakeholders.
- Increasing ***surveillance and detection*** of adverse events, disease outbreaks, natural disasters, and other emerging public health concerns.
- Heightening ***consumer product protection*** measures against the adverse effects of naturally occurring and manmade hazards.

⁴ Refer to Section C, “Organization and Assignment of Responsibilities” of this EOP for an overview of FDA organizational component roles and responsibilities during all hazards. Refer to the FDA EOP Incident Annexes for incident-specific Center/Office actions.

⁵ Examples of high-risk situations include designated National Special Security Events (NSSEs), developing public health emergencies and natural disasters, and NTAS alert levels.

- Ensuring the availability of *medical countermeasures* that prevent, diagnose, or treat the effects of disease outbreaks; biological, chemical, or radiological agents; and natural disasters.
- Increasing *surveillance of FDA-regulated products* used to prevent or mitigate adverse health effects related to the actual or potential incident.

FDA works closely with DHS and other Federal Agencies to coordinate the overall national effort to enhance the protection of critical infrastructure and key resources of the Nation, including food and agriculture defense. DHS serves as the coordinator of the Food and Agriculture Sector with the Government Coordination Council (GCC). The sector is a public-private partnership that combines expertise from several Federal Agencies as well as SLTT officials (representing agriculture, public health, and veterinary services) and the private sector (more than 100 trade associations and individual firms).

B.2.1.1 Surveillance, Detection, and Alert

Within the context of this plan, increased risk-based “surveillance and detection” is defined as an increase in the frequency, quantity, or detail of the ongoing systematic collection, analysis, and interpretation of public health data essential to the planning, execution, and evaluation of FDA emergency operations, closely integrated with the timely dissemination of these data to those responsible for prevention and control. FDA uses accumulated data from a variety of sources (e.g., international, Federal, and SLTT public health agencies; consumer complaints; regulatory inspections, investigations, and sampling; laboratory testing) for passive and active surveillance of regulated products and other public health concerns during day-to-day situations and for targeted preventive actions. The focus of these systems is to detect a “signal” to allow for additional information gathering and analysis or to track and trace a suspected or confirmed event within the agency’s jurisdiction. They support FDA’s primary mission, including identifying and reviewing adverse events and tracking and tracing product problems, and are used to facilitate counterterrorism and product safety and security activities as appropriate.

The Emergency Operations Center (EOC) is in a constant state of readiness during routine agency operations, maintaining 24 hours a day, 7 days a week (24/7) monitoring capability for surveillance and detection. OCM/Office of Emergency Operations (OEO) staff members assist with the detection of signals either as the direct point of contact (POC) for outside stakeholders or in support of the Centers and Office of Regulatory Affairs (ORA) and participate in meetings to identify emerging threats. OCM’s geographic information system (GIS) is another tool utilized to analyze health information and FDA activity data for spatially occurring patterns on a local, regional, or national level. FDA’s After-Hours Emergency Call Center serves as an additional resource to the EOC during non-duty hours, monitoring complaints and reports of problem products and triaging phone calls on pre-identified topics back to the EOC to be assessed by OCM/OEO staff to determine potential public health threats.

In addition, several databases and electronic information exchanges enable responsible FDA organizational components to collect and report out-of-the-ordinary information, monitor potential and ongoing situations, and determine whether agency emergency response activities are warranted (**Table B-1**).

Table B-1. Surveillance and Detection Systems Utilized by FDA

System	Description	Sponsoring Agency	FDA POC
Adverse Event Reporting System (AERS)	The AERS is a computerized information database designed to support FDA's post-marketing safety surveillance program for all approved drug and therapeutic biological products. FDA uses AERS to monitor for new adverse events and medication errors that might occur with these marketed products.	FDA	CDER
Biological Product Deviation Reporting (BDPR) System	The BDPR System reports errors and accidents in manufacturing of products, including testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product or a blood or a blood component, in which the safety, purity, or potency of a distributed product may be affected. Also, it includes deviations in manufacturing of human cells, tissues, and cellular and tissue-based products that relate to the prevention of communicable disease transmission, contamination, or other unexpected events.	FDA	CBER
BioWatch	BioWatch is a detection system for the release of biological agents in the air through a comprehensive protocol of monitoring and laboratory analysis.	CDC	OCM
CDRH Product Availability (Shortages) Database	The Shortages Database identifies and monitors supplies of certain devices that are or have the potential to be in demand.	FDA	CDRH
CFSAN Adverse Event Reporting System (CAERS)	The CAERS receives and monitors all post-marketing surveillance adverse events reports that directly affect CFSAN. These adverse event reports include foods, dietary supplements, cosmetic products, and food and color additives.	FDA	CFSAN
Counterfeit Alert Network (CAN)	The CAN is a coalition of health professional and consumer groups to disseminate educational guidance and alert messages about counterfeit drug incidents and measures to take to prevent exposure.	FDA	ORA/OCI
Electronic Laboratory Exchange Network (eLEXNET)	The eLEXNET is an integrated, Web-based information network that allows health officials at multiple government agencies engaged in food safety activities to coordinate and share laboratory analysis findings. It provides the necessary infrastructure for an early warning system that identifies potentially hazardous foods and enables health officials to assess risks and analyze trends. eLEXNET is the data capture and communication system for the Food Emergency Response Network (FERN) and is supported by the USDA and DoD.	FDA	ORA/OO
Emergency Operations Network – Incident Management System (EON-IMS) ⁶	The EON-IMS serves as the central hub for exchanging and relaying all incident-related information within the agency. Managed by OCM, this system integrates multiple data streams from other electronic systems (such as the FERN, eLEXNET, and Epidemic Information Exchange [Epi-X]) and from FDA laboratories and investigators and external agencies, into a coherent fashion during critical decision points. The EON-IMS creates a safety net that significantly reduces the probability that incidents will prevent FDA from accomplishing its objectives and minimizes the impact of these events on normal operations.	FDA	OCM
Epidemic Information Exchange (Epi-X)	The Epi-X is a secure, Web-based communications network that provides public health officials with up-to-the-minute information, reports, alerts, and discussions about terrorist events, toxic exposures, disease outbreaks, and other public health events. It provides a flexible search interface for researching outbreaks and unusual health events and for tracking information for outbreak investigations and response.	CDC	OCM

⁶ For more information on EON-IMS, refer to Section E, “Communications” in this EOP.



System	Description	Sponsoring Agency	FDA POC
Foodborne and Diarrheal Diseases Outbreak Summaries	FDA receives the weekly summaries on outbreaks from the CDC Foodborne and Diarrheal Diseases Branch to document ongoing investigations, current outbreaks, State(s) where the outbreak is occurring, and the serotype of the causal microorganism.	CDC	CFSAN
Foodborne Diseases Active Surveillance Network (FoodNet)	The FoodNet is a collaborative project of the CDC, 10 State Emerging Infections Program sites, the FSIS of the USDA, and FDA. It consists of active surveillance for foodborne diseases and related epidemiologic studies designed to help public health officials better understand the epidemiology of foodborne diseases in the United States.	CDC, USDA, FDA, State Health Departments	CFSAN
Food Emergency Response Network (FERN)	FERN is a network of Federal and State laboratories that analyze food samples in the event of a biological, chemical, nuclear, or radiological incident or large-scale contamination. FERN Federal partners include FDA, USDA, CDC, DHS/U.S. Customs and Border Protection (CBP), and the EPA.	FDA and USDA	ORA
Health Alert Network (HAN)	The HAN provides rapid and timely access to emergent health information and evidence-based practices and procedures for effective public health preparedness, response, and service on a 24/7 basis. It includes all 50 States, three large city health departments, three county health departments, eight territories, the District of Columbia, and multiple health organizations and major hospital networks.	CDC	OCM
Homeland Security Information Network (HSIN)	HSIN is a comprehensive, nationally secure, and trusted Web-based platform able to facilitate Sensitive But Unclassified information sharing and collaboration between Federal, State, local, tribal, private sector, and international partners. It interfaces with existing information sharing networks to support the diverse Communities of Interest engaged in preventing, protecting from, responding to, and recovering from all threats, hazards, and incidents. HSIN provides a collaborative environment that interoperates with mission area systems developed and managed by Federal, State, and local partners.	DHS	Centers, ORA, OCM
Integrated Consortium of Laboratory Networks (ICLN)	The ICLN was established to coordinate the Nation's laboratory networks to improve the response to acts of terrorism and other events requiring an integrated laboratory response. One outcome of the ICLN is the creation of an Integrated Response Architecture that provides, among other things, event notifications and updates, preparedness alerts, and situational reports through a secure Web portal.	DHS	ORA
Laboratory Response Network (LRN)	The LRN is a network of over 150 Federal, State, and local; military; food testing; environmental; veterinary; and international laboratories that are fully equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats and emergencies.	CDC	ORA and CFSAN
Manufacturer and User Facility Device Experience System (MAUDE)	MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports, user facility reports, distributor reports, and manufacturer reports. The online search allows you to search CDRH database information on medical devices that may have malfunctioned or caused a death or serious injury.	FDA	CDRH
MedWatch	MedWatch, the FDA Safety Information and Adverse Event Reporting Program, provides important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products. It allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices that they prescribe, dispense, or use.	FDA	CDER



System	Description	Sponsoring Agency	FDA POC
Mobile Laboratory (ML)	<p>FDA operates the following MLs:</p> <ul style="list-style-type: none">A microbiology lab to detect foodborne microbiological pathogens in food and drugs.A chemistry ML to detect pesticides, poisons, toxins, or other chemicals that could be used to deliberately contaminate food or drugs. <p>The ML allows FDA to transport and establish laboratory capabilities virtually anywhere in the continental U.S. and is capable of functioning as a self-contained regulatory laboratory. The microbiology ML tests products using enzyme-linked immunosorbent assay test kits and instrumentation and molecular Real-Time Polymerase Chain Reaction technologies. The chemistry ML contains sophisticated instruments to detect sub-ppm residues of pesticides or poisons in food. The ML has also received samples from State and local health departments as well as from other Federal and military branches of the Government. While the ML is a screening platform, all of the methods have been validated for the specific products and analytes/organisms tested. A fixed-site FDA laboratory supports further testing and confirmation of ML results.</p>	FDA	ORA
National Biosurveillance Integration System (NBIS)	The NBIS integrates all of the U.S. biosurveillance programs into a single system for providing a comprehensive, integrated biosurveillance and situational awareness for detecting agents and disease trends.	DHS	OCM/OEO
National Consumer Complaint System	FDA uses the National Consumer Complaint System to obtain complaint information from consumers about FDA-regulated products. Consumer Complaint Coordinators at FDA headquarters and District offices throughout the United States review complaints to identify product/problem trends and potential emerging public health issues.	FDA	OCM/OEO
New Drug Application (NDA) Field Alert Program	The NDA Field Alert Program is used to quickly identify drug products that pose potential safety threats. All drug manufacturers with approved NDAs and Abbreviated New Drug Applications (ANDAs) are required to submit Field Alert Reports to FDA if they find any significant problems with an approved drug.	FDA	CDER, ORA
The Pet Event Tracking Network (PETNet)	PetNet is a collaborative project between FDA and Federal and State government partners to provide a secure reporting/notification system, accessible by State and Federal government officials, which will allow for the exchange of information early in a disease outbreak that is associated with the consumption of adulterated pet food.	FDA	CVM
PulseNet	PulseNet is a national network of laboratories that performs DNA "fingerprinting" on foodborne bacteria. The network permits rapid comparison of patterns through an electronic database, helping to better detect the source of bacteria in foods. PulseNet helps public health authorities recognize when cases of foodborne illness are occurring at the same time in geographically separate locales.	CDC	CFSAN
Recall Enterprise System (RES)	RES is used by Center and District Office recall personnel to submit, update, classify, publicize, and terminate recalls. This online, searchable database allows users to enter real-time data on a recall event as it becomes available and track information and generate and disseminate reports of recall activities.	FDA	ORA
Safety Reporting Portal (also Reportable Food Registry [RFR])	RFR is an electronic portal for an owner, operator, or agent in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the U.S. to file a report about a product that is suspected will cause serious adverse health consequences or death to humans or animals. Initial RFR reports are sent to EON-IMS.	FDA	OCM/OEO, CFSAN
Vaccine Adverse Event Reporting System (VAERS)	The VAERS is a national vaccine safety surveillance program to detect possible signals of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events (possible side effects) that occur after the administration of U.S. licensed vaccines.	FDA, CDC	CBER

System	Description	Sponsoring Agency	FDA POC
Veterinary Adverse Drug Experience (ADE) Reporting System	The ADE Reporting System provides early warning to FDA for adverse effects not detected during pre-market testing of FDA-approved animal drugs. Reports of adverse clinical events from veterinarians and animal owners are entered into a computerized database for use by scientists to make decisions about product safety, which may include changes to the label or other regulatory action.	FDA	CVM
Veterinary Laboratory Response Network (Vet-LRN)	The Vet-LRN enhances collaboration between Federal and State agencies and veterinary diagnostic laboratories and provides additional laboratory capacity and expertise. The network contributes to the protection of the human food supply as laboratory findings of contamination of animals feed or drugs could signal potential contamination to human food.	FDA	CVM

B.2.1.2 Consumer Product Protection

Prior to confirmation of an incident, FDA may employ a number of activities designed to deter intentional and unintentional acts against FDA-regulated products and protect consumers from potential public health hazards.⁷ Through heightened and targeted preventive measures at various points in the processing and distribution chains, and by exercising the systems and networks to be used during emergency response operations, FDA can protect the safety and security of regulated products and protect consumers from harm. Activities in support of this effort, conducted in cooperation and collaboration with applicable FDA organizational components, Federal and SLTT partners, industry, academia, foreign governments, and international organizations include, but are not limited to, the following:

- Implementing risk communications with Government and industry partners.
- Prioritizing examination of food commodities based on potential for contamination (as determined by vulnerability assessments previously undertaken by FDA).
- Identifying entities handling specific FDA-regulated consumer products.
- Conducting targeted inspections and investigations and collecting samples.⁸
- Readying laboratory response and other scientific capabilities to analyze/test for chemical and microbiological agents.
- Tracing and intercepting specific imported and domestic products.
- Requesting the recall of drugs, biologics, medical devices, radiation-emitting devices, the food supply, or cosmetics that predictably could cause serious health problems or death (“Class I”) or such products that might cause a temporary health problem or pose only a slight threat of a serious nature (“Class II”).⁹
- Requesting the recall of tobacco products containing a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious adverse health consequences or death.

⁷ Incident confirmation includes conclusive laboratory analysis, field investigations, epidemiological data, or reliable information from other government agencies that triggers emergency response operations.

⁸ Detailed FDA investigation/inspection procedures can be found at www.fda.gov/ora/inspect_ref. Compliance references are located at www.fda.gov/ora/compliance_ref.

⁹ Recalls of products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws (“Class III”), will not by themselves activate this EOP.

- Providing additional guidance to food producers, processors, transporters, importers, retailers, food service establishments, and cosmetic processors on security measures to take to minimize the risk of tampering or other intentional contamination/adulteration and protect against the damaging effects of diseases and natural disasters.
- Working, as appropriate, with Federal and SLTT government agencies and international partners.
- Issuing warnings, alerts, advisories, and other advice to consumers, industry, foreign counterparts, and other international partners regarding food, drug, medical device, biological product, and tobacco product safety and animal health and soliciting feedback.

The FDA system for responding to the increased risk of an emergency or disaster impacting FDA-regulated products provides a significant increase in coverage, awareness, and preparedness through targeted preventive measures implemented by both headquarters and field offices and in coordination with other intergovernmental public health and medical partners. Collectively, these additional consumer protection activities provide for more protected supply and distribution chains and a better prepared national network capable of responding to an identified threat or hazard.¹⁰

B.2.1.3 Medical Countermeasures

FDA plays a vital and multifaceted role in securing the homeland through its broad regulatory oversight, monitoring infrastructure, and responding to terrorist attacks and naturally occurring emerging threats with timely and appropriate medical countermeasures. FDA fosters the development of safe and effective medical countermeasures to mitigate the effects of such threats by actively engaging industry, academia, and government partners. While all the FDA Centers and Offices have a role in the agency's counterterrorism mission, the three product Centers (i.e., Center for Biologics Evaluation and Research [CBER], Center for Drug Evaluation and Research [CDER], and Center for Devices and Radiological Health [CDRH]), as well as ORA and various organizations within the Office of the Commissioner (OC), play critical roles in ensuring the safety, effectiveness, quality, and availability of medical countermeasures. The Office of Counterterrorism and Emerging Threats (OCET) provides strategic leadership for agency-wide counterterrorism and emerging threats activities.

In situations where potentially useful medical countermeasures are available but not yet FDA-approved, licensed, or cleared for the particular use contemplated, OCET, in coordination with medical product Centers, can employ certain regulatory mechanisms to allow the use of these products during an emergency, as part of an expanded access Investigational New Drug (IND) application or Investigational Device Exemption (IDE), or under an EUA.

B.2.1.4 Increased Surveillance of FDA-Regulated Medical Products

Depending on the nature of an incident, FDA may increase its surveillance of FDA-regulated medical products used to prevent or mitigate adverse health effects related to the actual or potential incident. Such increased surveillance could be a result of conditions such as the use of a product by a larger or different population, the use of products for other than their labeled indication, or concerns about the potential development of resistance to a product such as antivirals or antibiotics.

¹⁰ For more information on FDA protection measures as part of the Nation's larger critical infrastructure protection efforts, refer to the "Agriculture and Food Critical Infrastructure and Key Resources Sector-Specific Plan" to the *National Infrastructure Protection Plan* located at www.dhhs.gov/ohsec/docs/nipp-ssp-food-ag-2010.pdf.

B.2.2 Response

Under the NPG, the response mission area includes those capabilities necessary to save lives, protect property and the environment, and meet basic human needs after an incident has occurred.

The “response” phase of FDA emergency operations includes those immediate and sustained actions to ensure the safety, efficacy, and availability of FDA-regulated products and to protect the public’s health throughout the duration of an incident. This phase generally involves the following four elements (**Figure B-1**):

1. **Gain and Maintain Situational Awareness**
 - **Alert and Notification.** Receiving information or intelligence confirming the development or occurrence of an incident and issuing notifications to agency stakeholders and partners.
 - **Assessment and Monitoring.** Performing initial and ongoing situation analysis, monitoring, and reporting.
2. **Activation and Deployment of Resources and Capabilities.** Directing and mobilizing FDA headquarters and field resources and capabilities, including EOC operational-level changes and implementation of the ICS in the field and/or headquarters.
3. **Coordination of Response Actions.** Conducting rapid and synchronized emergency response activities at headquarters and field locations.
4. **Demobilization.** Standing down FDA emergency response resources (i.e., personnel, facilities, equipment, and other materials support) and returning them to their original location and status.

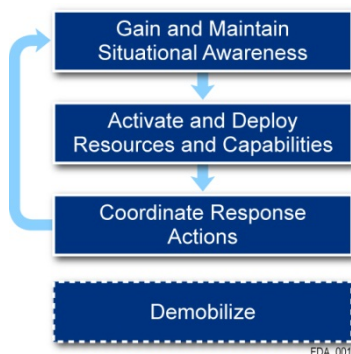


Figure B-1. FDA Emergency Response Elements

B.2.2.1 Gain and Maintain Situational Awareness

B.2.2.1.1 Alert and Notification

FDA may be alerted to a threat, hazard, or other significant event through a variety of means, including the surveillance systems discussed in **Table B-1** and/or directly from external Federal Agencies (e.g., the HHS Secretary’s Operations Center [SOC], Centers for Disease Control and Prevention [CDC], U.S. Department of Agriculture [USDA], DHS, and/or the Federal Bureau of Investigation [FBI]); international and SLTT public health agencies; industry; consumers; news media; and internal FDA organizational components. Any or all agency organizational components may receive word of a problem depending on the event’s scope and magnitude. Recipients of such information must handle it properly to ensure FDA is able to track and evaluate the situation. Failure to address a report in a timely fashion may delay emergency response and potentially exacerbate the incident.

The EOC serves as FDA’s focal point for monitoring and coordinating agency response activities related to developing and ongoing emergency situations, 24/7. The EOC is staffed by OCM/OEO staff members who work with the Centers and ORA to review information that may indicate potential or actual incidents, as well as quickly detect similarities in seemingly unrelated reports, and ensure that incident reports are treated in a consistent manner across FDA. The EOC also provides or acquires from a variety of sources the resources and capabilities necessary for FDA headquarters-level and interagency coordination that may be necessary when emergencies or disasters cross geographic and/or jurisdictional boundaries.

All reports of large-scale natural and manmade emergencies and significant alleged or actual adverse effects associated with FDA-regulated products require prompt reporting to the EOC staff of OCM/OEO. Upon receipt of an alert or warning, the EOC OCM/OEO staff will notify internal and external partners via a predeveloped, prioritized notification list specific to each particular emergency situation.

Certain types of incidents typically, but not necessarily always, should be reported to EOC staff of OCM/OEO as potential emergencies. These include incidents that:

- Involve life-threatening adverse events or deaths possibly related to use of drugs, biologics, medical devices, radiation-emitting devices, the food supply, or cosmetics.
- Involve life-threatening adverse events or deaths possibly related to use of an adulterated tobacco product containing manufacturing or other defects not ordinarily contained in tobacco products on the market.
- Involve a contaminant or pathogen associated with FDA-regulated products.
- Involve product distribution and/or injury, illness, or death across multiple States or geographic regions.
- Involve a considerable number of producers or manufacturers or a firm of considerable size and extensive product distribution.
- Arise in circumstances in which it is difficult to quickly identify the source of the problem.

B.2.2.1.2 Assessment and Monitoring

Once FDA officials receive word of an impending, ongoing, or resurgent emergency situation, they must gather enough information to determine the validity and extent of the threat or hazard and the agency’s roles and responsibilities within the situation. FDA headquarters and field organizational components work collaboratively with one another and with other government agencies and industry to rapidly evaluate the situation and make these determinations.

OCM/OEO is responsible for coordinating with applicable FDA headquarters and field units and external partners to formulate an initial incident assessment.¹¹ Results of this assessment may include a variety of situation reports (SitReps) and status reports, healthcare records, research and analyses, maps, and surveillance information. This critical information is passed through established reporting channels to allow agency decision-makers to develop situational awareness and establish a “common operating picture.” Using OCM’s GIS capabilities, an online or paper map-based common operating picture may be used to build and maintain situational awareness. The map-based common operating picture can visually depict response features with geographical reference in addition to the text information. Based on initial analysis of the threat or hazard, FDA will take steps to monitor the situation, identify and prioritize requirements, and/or activate available resources and capabilities. **Figure B-2** depicts the methodology agency officials use to assess an incident and determine whether additional response activities are warranted.

¹¹ At the time of the initial notification, an FDA organizational component or another government agency may already have completed a preliminary assessment of the emergency.

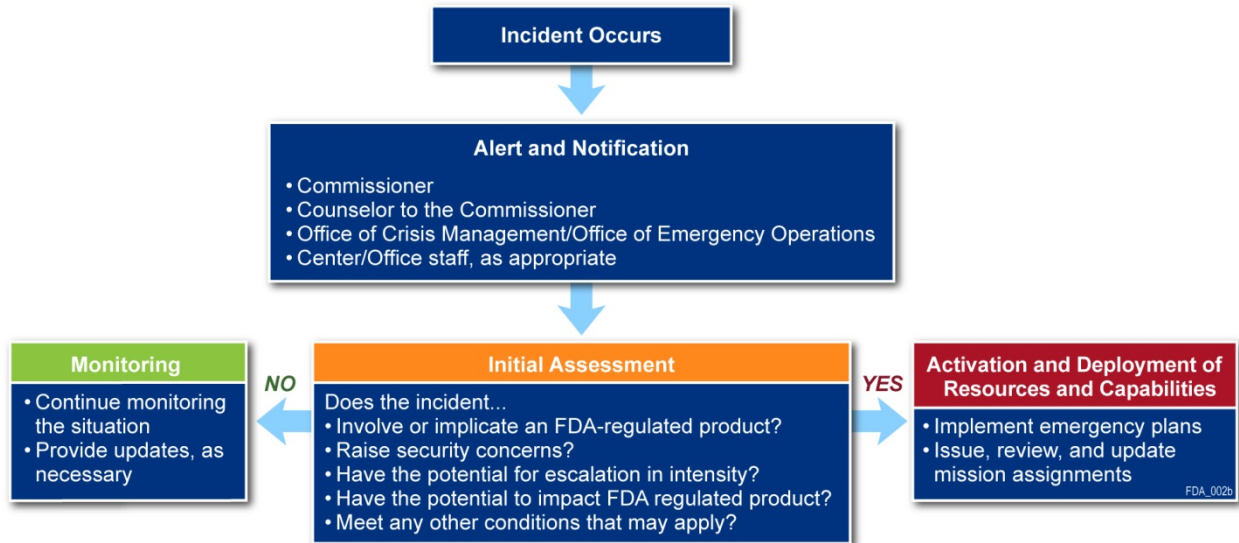


Figure B-2. FDA Emergency Response Decision Tree

Determining Regulatory Authority. It is important to note that a reported incident may or may not be subject to FDA authority. Therefore, one of the first discussions to take place will include a determination of whether FDA has regulatory authority. Some of the criteria potentially used in the assessment include:

- Whether an FDA-regulated product is implicated as the cause of the incident.
- Whether it is confirmed that FDA-regulated products have been or may be affected.
- Whether medical countermeasures are expected to be used in response.
- Whether interstate commerce of FDA-regulated products, as defined under the various statutes FDA enforces, is involved.
- Whether Federal or SLTT agencies and/or foreign governments have formally requested FDA assistance.

Once FDA determines that it has regulatory authority, it may manage the incident internally or function in a supporting role.¹² Although the agency may make an initial determination regarding authority and jurisdiction, it may continue to review and reconsider regulatory authority throughout an incident as it evolves, expands, or contracts.

B.2.2.2 Activation and Deployment of Resources and Capabilities

As the agency's central coordination point for emergencies, the FDA EOC operating status generally falls into one of three levels, depending on the severity or potential consequences of an incident or perceived threat (**Table B-2**). Confirmation of an incident with potential or confirmed public health impact may require activating a change in the EOC operational level from a readiness state of Operational Level 3 to Operational Level 2 or 1, depending on the scope of the incident. Center and Regional/District Office Situation Rooms, Command Centers, and Emergency Response Coordination Centers may follow the EOC operating levels or activate according to their individual emergency plans and procedures as appropriate.

¹² Refer to Appendix A and Appendix B of this EOP for detailed information on how FDA supports other Federal Agencies under the NRF.

Table B-2. FDA Incident Levels and EOC Operation Levels

Operational Level	Operating Status	Criteria	Examples
3	<ul style="list-style-type: none"> Routine awareness and response operations Normal staffing Regular work hours Readiness state 	Incident(s) involving FDA-regulated product(s) that, from a response and coordination viewpoint, are limited in complexity and scope such that the resources needed for response and/or coordination do not significantly impact normal operations for response/coordination. OCM and OCM/OEO coordinate with ORA and Center emergency coordinators. Generally, FDA's response and coordination actions are sufficient to respond effectively to the incident with no or limited internal and/or external coordination necessary.	<ul style="list-style-type: none"> Single person illness, injury, or consumer complaint with no or very few similar complaints in FDA systems Foodborne illness reports associated or implicated with FDA-regulated products Planning for NSSEs and other special events
2	<ul style="list-style-type: none"> Increased response operations Augmentation of EOC staffing may be necessary Extended work hours as needed Center Situation Room activation may be necessary Establishment of an Incident Management Group (IMG) may be necessary (EOC serves as resource to IMG) 	Incident(s) involving FDA-regulated product(s) that, from a response and coordination viewpoint, are of moderate complexity and scope such that resources needed for an effective response and/or coordination are beyond those ordinarily provided during the routine workday and/or beyond average staffing levels. The incident may require periodic or ongoing coordination with other external entities, in which case FDA may or may not be the "lead" responding agency for the incident. If additional staff and resources are not provided, response and coordination efforts would be somewhat adversely impacted, most likely in terms of response timeliness.	<ul style="list-style-type: none"> CDC report of microbial contamination in pharmacy-compounded drugs Ongoing foodborne illness outbreak involving one or more States or Regions (e.g., Salmonella Montevideo outbreak in 2009-2010 and Salmonella Enteritidis outbreak in 2010) H1N1 response 2009 NSSEs National-level or full-scale agency exercises
1	<ul style="list-style-type: none"> Escalated response operations Additional personnel (support and subject matter experts [SMEs]) Extended work hours likely, 24-hour operations possible (8- to 12-hour shifts) Center Situation Room provides EOC daily SitReps 	Incident(s) involving FDA-regulated product(s) that, from a response and coordination viewpoint, are of substantial complexity and scope such that the resources needed for an effective response and/or coordination exceed the Level 2 capability. Staffing levels, hours, and operations will likely be substantial to mount an effective response (to prevent or mitigate public health impact). Incidents may require significant coordination with external entities to optimize response. FDA may be the "lead" responding agency and/or may have a substantial support role to provide to another "lead" agency. Both field and headquarters response operations and/or coordination activities may require the establishment of formal organizational restructuring (e.g., ICS) to respond optimally.	<ul style="list-style-type: none"> Major natural disaster involving multiple States/Regions Ongoing foodborne illness outbreak or food contamination involving multiple States and increased complexity in product tracing involving multiple agencies Unknown contaminated drug product with serious adverse event Pet food contaminated human food or animal feed Terrorist event

Depending on the anticipated or actual size and complexity of an incident, activation of FDA emergency management resources may be required. The EOC, staffed by OCM and OCM/OEO (typically Operational Level 3), coordinates with ORA's headquarters and field components and the appropriate Center(s) in the review and analysis of information about threats and hazards and assists in the early recognition of emergencies, outbreaks, natural disasters, and terrorism or other criminal acts that may affect an FDA-regulated industry or product. This agency-wide coordination involves information collection and distribution, triaging complaints and alerts, issuing mission assignments (MAs) to organizational components, identifying and tracking needed resources, and communicating with external partners as they

request technical and material support. Additionally, the FDA EOC serves as the central link for coordination between FDA components and the HHS SOC, the CDC Director's EOC, USDA's EOC and/or Food Safety and Inspection Service (FSIS) Situation Room, and other Federal Departments/Agencies as appropriate.

B.2.2.2.1 Authority to Change EOC Operational Levels

The authority to change the operational level of FDA's EOC resides with the OCM Director, OCM/OEO Director, or his/her designee. The Commissioner or the Secretary or designee also may request a change in the operation level of the FDA EOC. Other agency emergency coordination units, such as Centers, shall activate their Situation Rooms at the discretion of senior management, such as the Center Director. Regional and District offices will establish Incident Management Teams (IMTs) at the discretion of the Regional Food and Drug Director (RFDD) or District Director (DD). FDA's EOC (OCM/OEO) shall be made aware when a Situation Room or IMT is activated in response to an incident. An increase in the EOC operational level may lead to the establishment of an Incident Management Group (IMG) to bring together additional resources and expertise to assume overall coordination for the response.

B.2.2.2.2 Conditions for Operational Level Change

Any of the following conditions could affect the operational levels of the EOC or activation of the FDA IMG:

- FDA has received credible intelligence or other confirmed information that an FDA-regulated product is the specific target of terrorism or other serious criminal activity.
- An incident involves a single or multiple FDA-regulated product(s) covering a large geographic or population area (more than one State) and requires the coordination of multiple agency organizational components.
- Two or more significant events have occurred at the same time.
- FDA-regulated products or facilities have been impacted by a natural or manmade disaster.
- A natural or manmade incident has triggered activation of the NRF, in whole or in part, and State or Federal agencies have formally requested assistance from FDA.
- Deliberate or accidental contamination of the human or animal food, medical products, or tobacco products supply has caused widespread illness, injury, or death to consumers.
- A widespread epidemic or pandemic disease outbreak or other public health emergency for which FDA has a designated support responsibility has occurred or is highly probable.
- DHS has raised the NTAS level to **Elevated** "Warns of credible terrorist threat against the United States," or to **Imminent** "Warns of credible, specific, and impending terrorist threat against the United States."

The FDA EOC will notify appropriate agency organizational components, the HHS SOC, and other key Federal partners when the EOC operational level has been changed or an IMG has been activated in response to an emergency.¹³ This activation announcement may include a status report explaining the rationale for the decision to change the EOC operational level or activate an IMG, a description of operating hours and staffing levels, and situation reporting requirements. After activation procedures commence, FDA may request additional resources and capabilities to augment emergency operations. This includes prioritizing and clearly communicating specific incident requirements to mobilize and

¹³ For detailed information on emergency alert and notification procedures, refer to Section E, "Communications and Information Management," of this EOP.

deploy emergency response staff to both internal and external locations. Requests for staffing will be made in writing by the OCM Director, OCM/OEO Director, or someone higher in the OC to Center and Office lead emergency coordinators or other senior officials within the organization. Representatives from specific headquarters Centers and Offices may be directed to relocate to the FDA EOC, other designated FDA locations, or other Federal Departments or Agencies. Interagency partners may also send representatives to the FDA EOC or other agency organizational components to perform liaison roles under existing memorandums of understanding (MOUs).¹⁴ In addition, FDA field organizations, such as Regional offices, District offices, branches, and resident posts may send personnel and specialized equipment to the FDA EOC, incident site(s), laboratories, or other designated locations to provide subject matter expertise and advice, conduct investigations and inspections, collect and analyze samples, and/or detain or destroy contaminated product(s).¹⁵

EOC Operations During Voluntary Isolation. The physical staffing of the IMG may take place within the location of the EOC or another designated location if needed. However, various conditions associated with a pandemic (i.e., quarantine, social distancing practices, and the need for staff to care for seriously ill family/friends), natural disaster, or other event impacting EOC members' ability to physically staff the EOC may make it necessary at times for IMG or EOC assigned staff personnel to carry out their duties from a remote location, such as their residence. The authority to operate the FDA EOC under "virtual" conditions resides with the OCM Director, OCM/OEO Director, or his/her designee.

B.2.2.3 Coordination of Response Actions

FDA personnel must perform a number of tasks and functions when responding to an incident. Some of these basic tasks may include performing initial and ongoing planning, managing and performing MAs, coordinating team response operations and resources, performing research and decision-making, and documenting and reporting information. Although FDA personnel accomplish most of these basic tasks over the course of the incident, their order of execution, the exact activities performed, and the individual or organization responsible will vary depending on the type and severity of the threat or hazard. Each involved FDA organizational component will be responsible for performing certain emergency actions based on its assigned mission and functions.¹⁶

FDA organizes emergency response operations in accordance with the concepts, principles, and terminology of the ICS, as defined within NIMS.¹⁷ Incident Command and subordinate Planning, Operations, Logistics, and Finance/Administration functions lay the foundation for the agency's implementation of the ICS during all-hazards response, at headquarters and field levels, and across geographic divides. The inherent design of this system enables rapid, scalable, and flexible agency-wide emergency management activities.

This section describes each of the components of a coordinated FDA emergency response. The agency's response strategy, while containing certain core activities, must be tailored to the specific requirements of each incident. (Refer to the Incident Annexes of this EOP for detailed information on FDA functions, activities, and organizational constructs for individual hazards.)

¹⁴ For more information on MOUs, refer to the FDA EOP Appendix I.

¹⁵ Refer to Section D, "Direction, Control, and Coordination," of this EOP for more information on agency emergency position assignments.

¹⁶ Refer to Section C, "Organization and Assignment of Responsibilities," of this EOP for more information on individual Center/Office roles and responsibilities.

¹⁷ For more information on the ICS, refer to www.training.fema.gov/EMIWeb/IS/ICSResource/index.htm.

B.2.2.3.1 Initial and Ongoing Response Planning

FDA conducts planning to organize its response structure, identify objectives and performance metrics, and coordinate the delivery of resource support. Planning is ongoing throughout the lifecycle of any incident and is adjusted as necessary to meet changing demands. It involves a blend of prescribed actions drawn from existing FDA emergency plans and procedural documents (e.g., hazard-specific incident annexes, SOPs, operations manuals, field guides) and real-time determination of the necessary course(s) of action. An agency Incident Action Plan (IAP) may be developed based on these actions to provide operational and tactical direction to FDA emergency personnel when responding.

The IAP is generally crafted by holding regular planning meetings throughout the incident, both in-person and via conference calls, with responsible headquarters and field units. Planning meetings seek to accomplish the following goals:

- Gathering, recording, analyzing, and distributing incident information in a manner that will facilitate: (1) increased situational awareness of the magnitude, complexity, and potential impact of the incident, emergency, or crisis; and (2) the ability to determine the resources required to resolve the situation.
- Formulating and prioritizing measurable incident objectives and identifying an appropriate response strategy that conforms to the legal obligations and management objectives of all FDA organizational components and/or external agencies involved.
- Determining the tactical direction, reporting mechanisms, timeframes, and specific resource requirements (i.e., personnel, specialized equipment, facilities, training and expert knowledge, and funding) for implementing selected strategies during the response period.

Through these planning meetings, FDA can coordinate the execution and evaluation of emergency activities, promote and maintain situational awareness (a “common operating picture”), track the progress of ongoing initiatives, and modify plans and procedures based on new and emerging information. For incidents involving both a headquarters (IMG) and field (IMT) response, IAPs will generally be developed by field units, while an Incident Coordination Plan (ICP) may be developed by the IMG that outlines incident objectives from a headquarters perspective (e.g., support of field operations).

B.2.2.3.2 FDA Field Response

For the majority of incidents involving FDA-regulated products, one or more FDA field offices may be involved in the response. The Districts in which the event is occurring (i.e., the physical location where people have been affected) will obtain necessary information for FDA to confirm the health hazard. In addition, the field offices will determine, plan, and conduct tasks and assignments over the course of the response.

Incident Management Team. A decision can be made to respond by implementing ICS at the field level, which involves the activation of one or more IMTs. Criteria for activating an IMT will be based on the conditions described in *Section A.3, “Scope and Applicability.”* The authority to mobilize an IMT resides with senior field officials, in consultation with senior ORA officials. Ideally, IMT activation should be coordinated with OCM or with the IMG if activated, but, at a minimum, these organizations should be notified whenever an IMT is being activated. An IMT may also be mobilized at the request of OCM or an IMG.

The IMT will be responsible for tactical operations (i.e., perform investigations/inspections, collect samples, and/or detain or destroy contaminated product) in accordance with the IAP it develops. In addition, as the IMT conducts its follow-up efforts, field offices will communicate investigational/inspectional findings of other potentially affected establishments with the firms’ home Districts and FDA headquarters emergency response entities described in the following section.

The IMT is led by a designated Incident Commander (IC) (see *Section D.1*, “Field Incident Command” for organizational elements). The field IC reports directly to the FDA Area Command, if activated, and provides continuous situational awareness to FDA’s EOC or an IMG (see *Section B.2.2.3.3*, “FDA Headquarters Response” for IMG description) through teleconference calls, emails, and/or SitReps. The IMT is responsible for managing the District’s or Region’s emergency response effort, coordinating actions and resources needed to follow up on the incident, and channeling all necessary communications to/from deployed field elements. Depending upon the nature and severity of the incident, additional field IMTs may be established to support geographically distant or functionally different emergency response operations.

Generally, the field IMT’s location could be set up at any of the FDA field offices near the site of investigational or inspection activities because of the accessibility to records and the availability of dedicated communications/information systems equipment. However, if the incident has destroyed or otherwise negatively impacted, or is projected to impact, the lead District’s office, or appropriate facilities are not available, consideration may be given to relocating the Incident Command Post (ICP) to an alternate facility, such as a predesignated District Office continuity of operations (COOP) site or other FDA District or Regional Office. A notification for reallocation of field staff between or among Districts shall be directed to ORA/Office of Operations (OO). As circumstances warrant, an IMT could be located at a location other than an established FDA Office, such as collocation with an HHS Incident Response Coordination Team (IRCT), FEMA Joint Field Office (JFO), or a facility near an establishment being inspected, as appropriate.

B.2.2.3.3 FDA Headquarters Response

Depending on the nature and complexity of FDA’s response to an incident, an intra-agency approach may be used to coordinate resources and incident-related information and to support incident management and agency policies. Depending on the scale of the incident, coordination will occur through the FDA EOC or an IMG operating from the EOC.

- **IMG.** An IMG is typically established when an incident involves multiple FDA organizational components or involves (or is anticipated to involve) complex incident management/coordination. The authority to establish FDA’s incident management structure, IMG, resides with the OCM Director, OCM/OEO Director, or his/her designee, in consultation with the Counselor to the Commissioner and appropriate senior Center and ORA officials. The IMG may be a hybrid structure conducting coordination and command dependent on the scope of the event. It is staffed by agency headquarters representatives (i.e., from the OC, ORA, and/or the FDA product Centers) and, as appropriate, FDA field staff and/or external agency liaisons. The IMG staffing is organized consistent with the principles of NIMS. An Agency Incident Coordinator (AIC) is designated to oversee the IMG, including development and implementation of a headquarters ICP and the coordination of FDA headquarters resources and capabilities to respond to the event, as needed. Subordinate Command and General Staff, comprising representatives from headquarters Centers and Offices, are also established to assist the AIC in executing emergency functions under the specific conditions at-hand.¹⁸ The AIC reports directly to the Commissioner or the Commissioner’s designee, such as the Counselor to the Commissioner, or an Agency Executive Group (AEG). An AEG may be set up to provide guidance on policy issues and resolve issues involving competing resources. For a further description of the AEG, see *Section D*, “Direction, Control, and Coordination.”¹⁹

¹⁸ For detailed information on how the FDA organizes and staffs emergency response operations, refer to Section D, “Direction, Control, and Coordination,” of this EOP.

¹⁹ The use of the terms “Incident Management Group” and “Agency Executive Group” should be reserved for use only as defined in the FDA EOP. Use of ICS principles across FDA is encouraged; however, the terms IMG and AEG only apply to the incident structure activated by OCM/OEO and are used as described above.

The scope of the incident may call for activation of an internal FDA Joint Information Center (JIC). This is a collocated group of representatives from Centers and Offices involved in the event that are designated to handle public information needs. For a further description of the FDA JIC, see *Section D.2.2.4.1, “Units.”*

- **EOC.** The FDA EOC is the physical location at which the coordination of information and resources to support incident management activities normally takes place.

FDA EOC. The FDA EOC serves as the agency-wide focal point for emergency operations coordination and dissemination of information, whether staffed by OCM/OEO personnel or an IMG. The FDA EOC monitors ongoing events, processes complaints and alerts, issues MAs to FDA organizational components, coordinates overall agency emergency management operations, and communicates with interagency partners to provide technical and material support.²⁰ The FDA EOC staff facilitates contact between applicable headquarters and field emergency personnel and provides frequent and formalized communications/reporting to senior agency officials and organizational components, as well as the HHS SOC and other external partners, regarding the status of FDA emergency response activities.

The FDA EOC provides a physical central location from which headquarters personnel can provide agency-wide coordination and executive decision-making in support of the incident response. The FDA EOC staff does not command or control the agency’s response, but carries out the coordination function for complex incidents or multiple incidents occurring simultaneously through:

- **Information Collection, Evaluation, and Dissemination.** Collecting, analyzing, interpreting, and distributing information from/to various internal and external sources.
- **Priority Setting.** Ensuring that agency response systems are interconnected and complementary, reinforcing interoperability among the various organizational components, making the response more efficient and effective by coordinating available resources, and making decisions based on agreed-upon policies and procedures.
- **Resource Coordination.** Identifying and acquiring needed resources and allocating existing or known resources.
- **Communications Facilitation.** Establishing and maintaining intra- and interagency interoperable communications.

Centers. The FDA product Centers are responsible for scientific evaluations and for programmatic decisions and policy development within their respective program areas. Their professional staff includes clinical, scientific, and manufacturing process experts. This expertise (analytical, laboratory, sampling procedures, subject matter expertise, and industry knowledge) is routinely utilized for critical consultation and decision-making should an incident occur.

Centers may maintain a Situation Room or Coordination Center consisting of Center-selected subject matter experts (SMEs) to be led by a Center Emergency Coordinator (CEC) who reports to the Center Director and coordinates directly with the FDA EOC. The CEC serves as the focal point for internal and external Center communications during emergencies and disasters and is responsible for providing regular status and SitReps to the FDA EOC as requested. FDA Centers participate in agency emergency operations when the response includes, or may include, regulatory activities or products under their jurisdiction. During some large-scale or catastrophic incidents, CECs or other Center personnel may be directed to report to the FDA EOC to support initial or prolonged emergency operations as part of an IMG.

For further information about the Center’s responsibilities during an emergency, please see *Section C.3, “Office of Foods and Veterinary Medicine”* of this EOP.

²⁰ The composition of FDA EOC staff will change depending on specific incident requirements.

ORA. Any information received by ORA regarding the incident or ongoing field activities will be shared and/or discussed, as appropriate, with staff operating from the FDA EOC and the Commissioner or the Commissioner’s designee as appropriate. Additionally, ORA, working with the responsible Centers, will develop, issue, and approve any new or revised regulatory policy required during the course of the event.

For further information about ORA’s responsibilities during an emergency, please see *Section C.2*, “Office of Operations” of this EOP.

B.2.2.3.4 Mission Assignments in Support of State and Local Response

Requests for support from State and local agencies can be made directly to the agency or, in the case of a declaration of a major disaster or emergency under the Stafford Act, through FEMA. In order to assist SLTT agencies with such requests, FDA has developed Pre-Scripted Mission Assignments (PSMAs), which can be used to expedite the submission of requests when a major disaster or emergency has been declared. These requests include laboratory analysis, investigational, sampling collection, subject matter expertise, and training related to drugs, biologics, medical devices, radiation-emitting devices, tobacco, the food supply, or cosmetics. See **Appendix C**, “Processing Mission Assignment Sub-Taskings” for procedures on executing MA sub-taskings and for the list of the PSMAs.

B.2.2.3.5 Medical Countermeasures: EUA and Expanded Access

For certain events, the Commissioner may authorize the use of an unapproved medical product or the unapproved use of an approved medical product during a declared emergency, which may involve a heightened risk of attack against the public or U.S. military forces, has a significant potential to affect national security or the health and security of U.S. citizens living abroad, or the identification of a material threat sufficient to affect national security or the health and security of U.S. citizens living abroad. This can be due to a naturally occurring disease or a CBRN agent.^{21,22} An EUA may be issued only after the Secretary has declared an emergency justifying the authorization to use a product, based on an appropriate determination made by the DHS Secretary, Secretary of Defense, or HHS Secretary, as required by the Project BioShield Act of 2004 as amended by the Pandemic and All Hazards Preparedness Reauthorization Act.^{23,24}

When a countermeasure has not yet been approved, licensed, or cleared because the safety, effectiveness, and/or quality have not been fully established, FDA may permit its use under an IND application or IDE²⁵ through expanded access mechanisms, or under an EUA.

Although FDA clearly defines most medical countermeasure regulatory jurisdictional responsibilities, several jurisdictional situations require explanation. CBER regulates all vaccines and blood derivatives for human use, and the USDA regulates those for veterinary use. CDER regulates all drugs for human use, and the Center for Veterinary Medicine (CVM) regulates all drugs for veterinary use. CDRH regulates the majority of clinical diagnostics; however, CBER regulates a specialized subset of in-vitro diagnostics (IVD) involved in the safety of the blood/tissue supply. Therapeutic biologics are regulated by multiple Centers, and questions shou

²¹ The Biomedical Advanced Research and Development Authority (BARDA), within HHS Office of the Assistant Secretary for Preparedness and Response, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies (www.phe.gov/about/barda/Pages/default.aspx).

²² Medicalcountermeasures.gov facilitates communication between Federal Government Agencies and public stakeholders to enhance the Nation’s public health emergency preparedness (www.medicalcountermeasures.gov/).

²³ The most current FDA guidance on EUAs can be found at www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm.

²⁴ FD&C Act, Section 564, *Authorization for Medical Products for Use in Emergencies*.

²⁵ FD&C Act, Section 561, (b) and (c): *Expanded Access to Unapproved Therapies and Diagnostics*.

ld be addressed to the appropriate Center. In instances where Center-specific jurisdiction within FDA is unclear, the FDA Office of Combination Products (OCP) will decide which FDA Center possesses regulatory jurisdiction.

During high-risk or threat situations, responsible OC Offices and FDA Centers and Offices shall perform the following general functions related to medical countermeasures:

- Monitoring and updating the status of product availability and relevant manufacturing information.
- Facilitating the availability of safe and effective drugs, therapeutic biologics, vaccines, cellular- and tissue-based therapies, diagnostic devices, and other biological products to be used as counter-measures.
- Collaborating with, as permitted, Federal and SLTT public health agencies and regulated industry regarding product stockpile issues, including labeling, appropriate usage, product performance, monitoring, use in special populations, and other evolving issues.
- Conducting prospective discussions about emergency use of products and the appropriate regulatory mechanism for their use and the submission of data (i.e., EUA, IND, IDE, or Master File) on the product.
- Ensuring product recipients will be provided information (1) adequate to obtain informed consent (for IND and IDE products), or (2) as required by the EUA (e.g., that the product is under EUA and indicates the known and potential risks and benefits of taking or refusing the product).
- Providing advice on identifying potential contaminants of drugs and therapeutic biological products and advising how to test for quality and purity.

B.2.2.4 Demobilization

As the need for full-time incident response coordination wanes, FDA will assess the situation to determine whether to continue or terminate emergency operations.²⁶ This decision includes identifying whether consumer product safety and security and public health protection objectives were achieved and an orderly, safe, and efficient return of FDA resources (i.e., activated or deployed personnel, facilities, and equipment) to their original locations and/or operating status is warranted. In making this decision, FDA coordinates with and seeks input from appropriate experts and stakeholders. As a result, FDA organizational components may resume normal business operations and transition to short- and long-term recovery. Demobilization of an IMG will be announced through written correspondence from the AIC to all IMG members, generally as part of a written demobilization plan developed by the IMG Planning Section. The FDA EOC, or IMG, if activated, should be notified whenever an IMT has been demobilized.

Depending on the incident, resurgence may occur, and any period of transition back to normal operations could be disrupted. When this occurs, the agency will begin a new “notification and alert” period for emergency response and a change in EOC operational levels may occur.

Transition back to normal operations, after initiating and conducting an emergency response, will occur in stages and will correspond to the recovery of affected communities, FDA-regulated firms, and the Nation as a whole.

²⁶ Only the Commissioner, his/her authorized designee, or the AIC may formally terminate agency-wide emergency response operations. However, Center Directors, RFDDs, and DDs, through their respective emergency coordinators, are authorized to demobilize emergency personnel within their organizational components (e.g., IMTs).

B.2.3 Recovery

Under the NPG, the recovery mission area includes those capabilities necessary to assist communities affected by an incident in recovering effectively.

The “recovery” phase of FDA emergency operations includes short- and long-term actions to ensure and restore the safety, efficacy, and availability of FDA-regulated products and to protect the public’s health. To accomplish this, FDA supports HHS in the execution of the NDRF and the two Recovery Support Functions (RSFs)—Health and Social Services and Infrastructure Systems—that require HHS coordination or support.

As Federal ESF operations conclude, requests for more detailed assessments, technical assistance, and longer term coordination fall under the recovery mission. Subject matter expertise and technical assistance can be provided to address issues that impact FDA-regulated industries. FDA and Federal supporting agencies will work with SLTT entities to provide a coordinated and consistent approach to recover from an incident. FDA will collaborate and maintain communication with other government agencies, industry, the public, and the media particularly concerning any long-term affects associated with the event.

Recovery objectives that support Federal and SLTT agencies for each RSF are outlined below:

- **Health and Social Services**
 - Inspect or investigate FDA-regulated facilities and collect and analyze samples of FDA-regulated products for the overall recovery operation as needed.
 - Conduct prolonged inspection, sample collection, and laboratory analysis activities in support of SLTT agencies that are specifically related to a disaster but deemed ineligible under the Stafford Act (e.g., inspections of retail food establishments and pharmacies).
 - Manage a potentially large number of samples of FDA-regulated products, including long-term sampling associated with the health effects of natural and manmade disasters.
 - Oversee product destruction and product reconditioning or rendering as appropriate.
- **Infrastructure Systems**
 - Identify key pharmaceutical and medical device facilities and determine if any supplies of drugs, biologics, or medical equipment have been or will be critically impacted.
 - Facilitate the availability of critically needed medical products by identifying alternate products or sources of products.
 - Identify key facilities that manufacture/process, pack, or hold food for human or animal consumption and determine if any are critically impacted.
 - Provide clear and consistent information to assist industry in understanding and complying with regulations in a post-disaster environment.

Dependent on the recovery objectives and the level of coordination needed, the FDA IMG will determine if FDA EOC or FDA JIC resources are needed to support the functioning of the IMG and recovery efforts.

As the need for recovery coordination wanes, FDA will assess whether consumer product safety and security and public health protection objectives were achieved. The transition back to a steady state operation will occur in stages and will correspond to the reestablishment of public confidence in FDA-regulated products. In regard to the recovery of FDA-regulated industry, it may be more appropriate that

long-term recovery activities requiring FDA involvement be coordinated by agency components other than OCM/OEO or an IMG.

The text of the NDRF is available at www.fema.gov/pdf/recoveryframework/ndrf.pdf.

B.2.3.1 Evaluation of Response

Following any emergency or disaster, FDA organizational components will discuss how the agency handled the incident and seek input from appropriate experts and stakeholders. Participants analyze emergency actions and responsibilities, resolve any deficiencies, mitigate consequences, and anticipate and address any long-term affects of the incident. In addition, organizational policies, plans, and procedures are updated as needed, incorporating lessons learned and best practices captured during the event.

Following the termination of response activities that involved an IMG, OCM works with stakeholders to conduct a lessons learned analysis to identify the following:

- Strengths and weaknesses of key response activities performed during the incident, including agency measures to protect public health.
- Resource needs (e.g., personnel, equipment, training).
- Improvements to emergency response plans and procedures.
- Strengths and weaknesses of agency communications, which could include intra-agency and interagency communications as well as communications with specific stakeholder groups, such as industry, consumers, and the news media.
- Needed modifications toward regulatory policy, laboratory and field operations, and research activities.
- Any other needed improvements to overall preparedness.

As an important part of this process, it is generally advisable that when an IMG has been activated, the AIC or his/her designee (usually the Planning Section Chief) conduct an event Hot Wash, which is a brief facilitated session to obtain IMG members' verbal feedback on the incident. This session should be conducted prior to the release of the majority of the IMG staff. This session is coordinated with the OCM staff preparing the incident After Action Report (AAR) and feedback received provided for use in developing the report.

A final AAR draws conclusions from data collected. All FDA Centers and Offices should submit their input to the FDA OCM Director. All relevant parties within FDA receive the final report. With regard to the recovery of FDA-regulated industry, it may be more appropriate that long-term recovery activities requiring FDA involvement be coordinated by agency components other than OCM/OEO.



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C. ORGANIZATION AND ASSIGNMENT OF RESPONSIBILITIES

This section identifies the general roles and responsibilities of FDA headquarters and field organizational components, including those that assist in preventing and protecting against, responding to, and recovering from all hazards. FDA staff work closely with one another and with governmental and industry partners to ensure the safety, efficacy, and security of FDA-regulated products that mitigate the public health effects of an emergency or disaster in the United States or worldwide, using novel and expeditious approaches to product regulation for optimized availability and use in all populations.

FDA functions are organized into four directorates:

1. OO oversees administrative functions such as human resources (HR), facilities, information technology (IT), and finance.
2. The Office of Foods and Veterinary Medicine (OFVM) provides oversight of FDA's food and feed programs as well as leads the implementation of the FDA Food Safety Modernization Act of 2011 (FSMA). OFVM includes the Coordinated Outbreak Response and Evaluation (CORE) Network, CVM, and the Center for Food Safety and Applied Nutrition (CFSAN).
3. The Office of Medical Products and Tobacco (OMPT) provides high-level coordination and leadership across the Centers for drugs, biologics, medical devices, and tobacco products. This Office also oversees special medical programs.
4. The Office of Global Regulatory Operations and Policy (OGROP) is focused on globalization and import safety of food and drug production and supply. The Office provides direction and support to ORA and the Office of International Programs (OIP).

The FDA product Centers are discrete management entities and are responsible for the regulation of a defined set of products. Their professional staff includes clinical, scientific, and regulatory experts. This expertise (analytical, laboratory, sampling procedures, subject matter expertise, and industry knowledge) is available for critical consultation should an emergency or disaster occur. The Centers are responsible for scientific evaluations, decisions in conjunction with ORA in response-focus based on scientific evaluations, and policy decisions within their respective program areas. FDA product Centers participate in emergency operations when the agency response includes, or may include, regulatory activities or products under their jurisdiction.

Figure C-1 outlines FDA’s overall organizational structure and is followed by a brief description of the emergency functions performed by all responsible organizational components.²⁷ Refer to individual Center/Office emergency plans and procedural documentation, as applicable, for more detailed information on emergency actions.

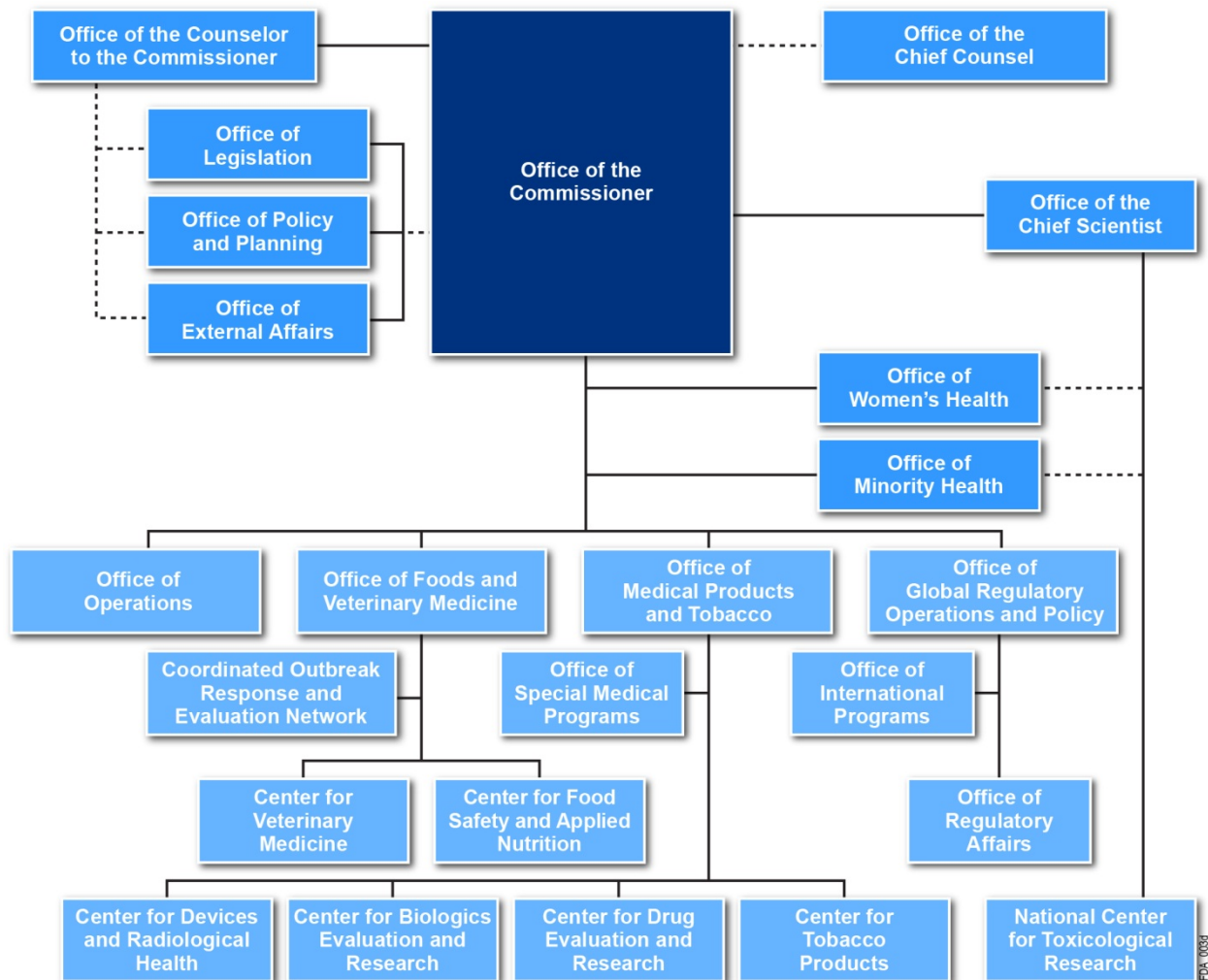


Figure C-1. FDA Organizational Chart

²⁷ Those FDA organizational components without defined emergency roles or responsibilities are not described within this EOP.

C.1 OFFICE OF THE COMMISSIONER

The OC (see **Figure C-2**) provides centralized direction and management services for agency-wide programs to ensure that FDA's consumer protection efforts are effectively managed within its legal and regulatory framework and those available resources are put to the most efficient use. The OC also provides policymaking, program direction, coordination and liaison, and expert advice to agency leadership and programs in support of FDA's science-based work. The Office includes the Commissioner and Deputy Commissioners.

Office of the Chief of Staff

The Office of the Chief of Staff (OCoS) coordinates staff activities in the OC and serves as the principal liaison to HHS. The Office advises and provides integrated policy analysis and strategic consultation to the Commissioner and Deputy Commissioners, and other senior FDA officials, on activities and issues that affect significant agency programs, projects, and initiatives. OCoS provides senior-level leadership and guidance on issues and actions tied to the agency's communications with HHS and the White House, including correspondence for secretarial signatures.

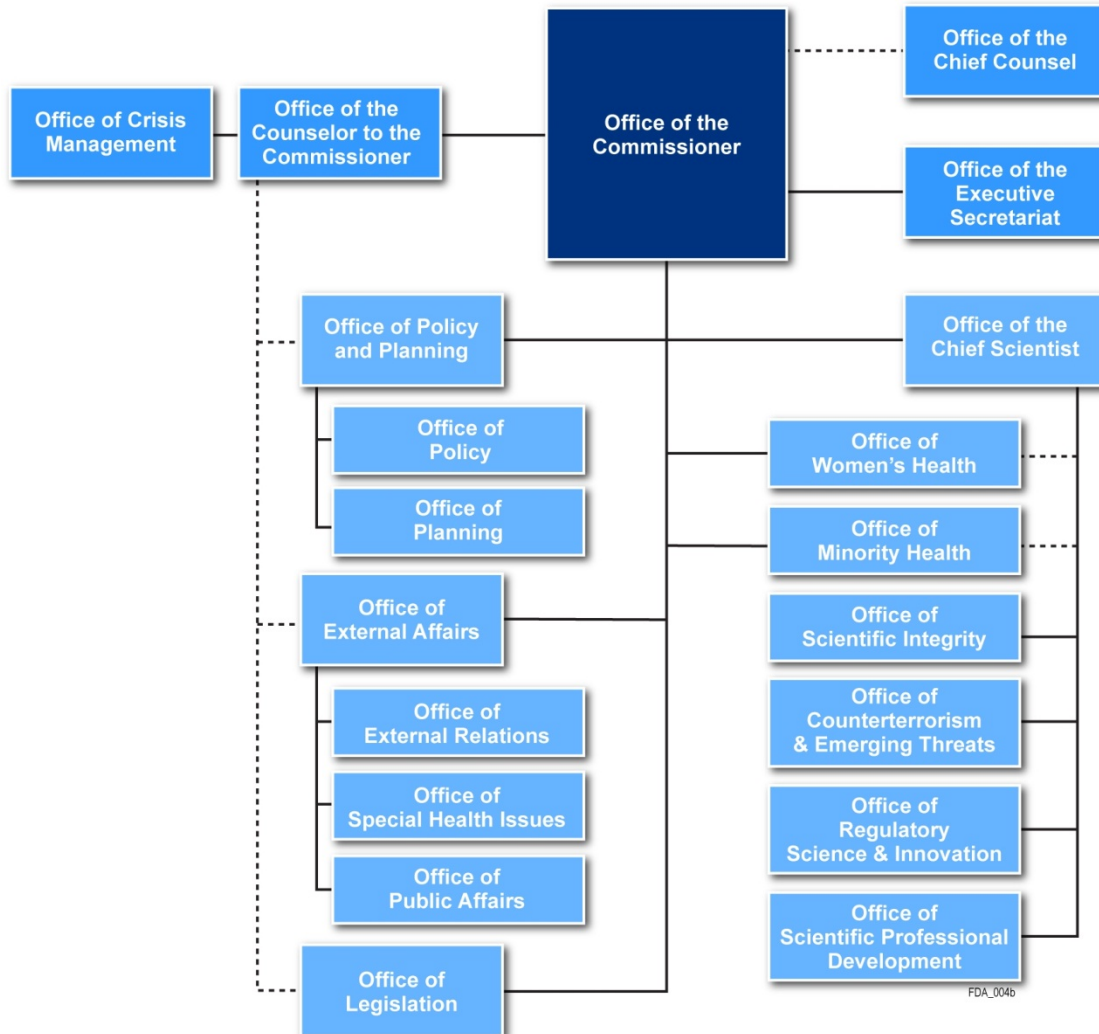


Figure C-2. FDA OC Organizational Chart

C.1.1 Office of the Executive Secretariat

The Office of the Executive Secretariat (OES) provides direct support to the Commissioner, including preparation of briefing material and background information for meetings, correspondence management and control, and preparation and transmittal of information advisories and alerts to HHS. The Office develops and maintains information to monitor the Commissioner's and FDA's goals and priorities.

In addition, OES is responsible for:

- **Dockets Management.** The Dockets Management staff will continue to post critical public information to the *Federal Register* in accordance with Federal law.
- **Freedom of Information Act (FOIA).** The Division of Freedom of Information will continue to respond to new requests and denials, provide appeals and litigation support and FOIA and Privacy Act policy, and will assist the Office of Media Affairs (OMA) as needed to review possible public announcements prior to their dissemination.

C.1.2 Office of the Chief Counsel

The Office of the Chief Counsel (OCC) is composed of litigators and counselors. Litigators handle both civil and criminal cases, participating in case development; drafting pleadings, motions, and briefs; and conducting discovery and trials. Counselors provide legal opinions to the major programs of the agency—drugs, foods, biologics, devices, veterinary products, tobacco products, and enforcement. They participate in rulemaking proceedings, legislative matters, policy deliberations, and international negotiations. In addition, FDA attorneys are involved in explaining agency programs to Congress, regulated industry, and the public. In an emergency or disaster, OCC is responsible for, but not limited to, the following activities:

- Providing FDA organizational components with legal counsel on incident-related regulatory activities; examples include EUAs, marketing of medical countermeasures, and human subject protection (HSP).
- Providing FDA organizational components with legal counsel related to sharing of information with other government agencies and the public with proper protections (e.g., for trade secrets and confidential commercial information).
- Advising ORA and other relevant agency organizational components on inspections and enforcement matters related to foods, drugs, biologics, medical devices, radiological products, animal drugs/feed, cosmetics, and tobacco products.
- Coordinating with the HHS Office of the General Counsel (OGC) on FDA-related issues as appropriate (e.g., on grants and contracts and on legal issues arising from activities of other HHS Operating Divisions [OPDIVs] in relation to FDA activities).
- Working with other government agencies and their attorneys, Congress, and the U.S. Courts on FDA-related issues (e.g., the U.S. Department of Justice [DOJ], FBI, Federal Trade Commission [FTC], USDA, U.S. Environmental Protection Agency [EPA], U.S. Department of State [DOS], and the U.S. Postal Service [USPS]; State Attorney Generals' offices; congressional oversight and appropriations committees; and Federal and State courts).
- Providing legal advice and assistance to the Office of the Secretary on matters within the expertise of the OCC.

C.1.3 Office of Legislation

The Office of Legislation (OL) directs and manages FDA's legislative needs, pending legislation, oversight activities, and congressional relations consistent with the mission of the agency. In an emergency or disaster, OL is responsible for, but not limited to, the following activities:

- Keeping Congress apprised of FDA actions in coordination with the HHS Office of the Assistant Secretary for Legislation.
- Responding to congressional Requests for Information (RFIs).
- Arranging and supporting congressional meetings, briefings, and hearings.

C.1.4 Office of Policy and Planning

The Office of Policy and Planning (OPP) provides advice to the Commissioner and other key FDA officials on matters relating to strategic direction, policy, development of regulations and guidance, legislative issues, planning and evaluation activities, and budget. OPP manages FDA's Advisory Committee program, coordinates the publication of agency rules and notices in the *Federal Register*, serves as the agency focal point for policy development, and helps ensure agency components adhere to FDA policies and regulations. This Office participates with the Commissioner in the formulation of the budget, basic policies, and operational philosophy that guide FDA in effectively achieving its goals and meeting its responsibilities.

C.1.4.1 Office of Policy

The Office of Policy is responsible for advising the Commissioner and other key agency officials on matters relating to agency policy and on regulations and industry guidance development.

C.1.4.2 Office of Planning

The Office of Planning develops programs and systems to evaluate overall FDA program accomplishments against objectives and priorities, recommending changes as necessary.

C.1.5 Office of the Counselor to the Commissioner

The Office of the Counselor to the Commissioner provides a leadership role in advocating for and advancing the Commissioner's priorities. This Office provides top-level leadership for the development and management of emergency and crisis management policies and programs for FDA to ensure that a structure exists for FDA to respond rapidly to an emergency or crisis situation in which FDA-regulated products need to be utilized or deployed.

C.1.5.1 Office of Crisis Management

OCM serves as FDA's focal point for coordinating emergency response activities involving FDA-regulated products and in situations when agency resources need to be used or deployed. It coordinates intra- and interagency activities related to emergency preparedness and response and security operations. OCM assists in the development, management, and coordination of incident management policies and programs for FDA to ensure that a structure exists to respond rapidly and effectively to all hazards. OCM consists of a Director; Immediate Office; Program Operations and Coordination Staff (POCS); Emergency Planning, Exercises, and Evaluation Staff (EPEES); and OCM/OEO. OCM/POCS provides GIS support to the agency and manages the FDA EOC, FDA After-Hours Emergency Call Center, GeoWeb (a geographic information portal), and the Emergency Operations Network – Incident Management System (EON-IMS). OCM/EPEES is responsible for emergency plans, exercises, and evaluation. Additionally, OCM serves as a coordinator to the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), providing situational awareness of all FDA-related emergencies, and

ensures FDA's emergency operations procedures are in alignment with national and HHS procedures. During an emergency response, OCM supports the agency with the following activities:

- Provides Offices and Centers with maps and spatial analysis through GIS for use in strategic planning of agency emergency response activities. Additionally, GIS provides situational awareness during a response in the form of maps that depict FDA-regulated industry, locations of FDA response activities, and other areas of interest. GIS allows responders to explore spatial trends in information and visually communicate information that can support and improve decisions.
- Oversees the FDA After-Hours Emergency Call Center, which provides after normal hours service for responding to public inquiries and reports related to FDA-regulated products as well as surge capacity service for managing increased volumes of inquiries due to an incident involving an FDA-regulated product.
- Manages FDA's EOC, staffing it with personnel from OCM/OEO; when the EOC is activated, OCM augments EOC operations with personnel from relevant Centers and Offices to monitor emergency situations, triage complaints and alerts, issue MAs to organizational components, coordinate overall agency response operations, and communicate with external partners requesting technical and material support.
- Coordinates the agency's evaluation or after action review of FDA's responses to emergencies and crisis situations to determine appropriate internal and external referral for further action and recommended changes in agency policies and procedures.
- Maintains situational awareness on intelligence matters related to FDA-regulated products.
- Advises and assists key FDA officials on counterterrorism and intelligence matters.

C.1.5.1.1 Office of Emergency Operations

OEO is staffed with emergency coordinators and serves as the central coordination point for the agency's response to adverse events, foodborne illnesses, injuries, product tampering, and manmade and natural hazards. It serves as the agency focal point for emergency preparedness and response operating the 24/7 emergency response system. OEO reviews and assists in the analysis of preliminary information about threats and hazards and assists in the early recognition and agency notification of emergencies, outbreaks, natural disasters, and terrorism or other criminal acts. Part of OEO responsibilities is to manage the national Consumer Complaint System, which monitors reports of problems with FDA-regulated products for potential emergencies. Another is to participate in weekly National Biosurveillance Integration Center (NBIC) conference calls sponsored by DHS to provide a secure forum for interagency information sharing for early recognition of biological events of national concern, both natural and manmade, to make a timely response possible.

In an emergency or disaster, OEO's staff members are responsible for, but not limited to, the following activities:

- Tracking trends and potential threats associated with FDA-regulated products such as after-hour calls and consumer complaints.
- Triageing consumer complaints and emergency alerts.
- Coordinating, monitoring, documenting, and reporting on all agency response activities and inter-agency communications.
- Coordinating resource requirements with headquarters Centers and Offices and issuing assignments to the field.

- Communicating with Federal Agencies (e.g., HHS SOC, CDC, USDA, DHS, National Oceanic and Atmospheric Administration [NOAA], EPA) as they request technical and material support from FDA.
- Providing core staff for the operation of FDA's EOC and liaisons to the HHS SOC.

C.1.6 Office of External Affairs

The Office of External Affairs (OEA) is responsible for the following activities:

- Serves as the central point of communication and education about the FDA's public health and regulatory activity. This includes the development, coordination, and leadership of all FDA communications and outreach efforts to the news media, health professionals, patient advocates, industry, States, consumer groups, and the general public. OEA also serves as the focal point for internal employee communications, speechwriting, creative and editorial services, and best practices in digital and Web technology.
- Advises the Commissioner, Deputy Commissioners, and other key agency officials on FDA's communications to the media, Congress, and the general public on issues that affect agency-wide programs, projects, strategies, partnerships, and initiatives.
- Advises and assists the Commissioner and other key officials on all public information programs; acts as the focal point for disseminating news on FDA activities and as a liaison with the U.S. Public Health Service (USPHS) and HHS on public information programs.
- Advises the Commissioner, Deputy Commissioners, and other senior staff throughout FDA on sensitive and controversial programs and initiatives that affect external stakeholder groups; provides historical expertise and records to inform those decisions.
- Provides communication expertise and state-of-the-art digital guidance and tools for application across the agency.
- Serves as a liaison between FDA and health professional and patient advocacy organizations to solve problems and address concerns these groups have with agency policies and programs related to human and medical product development and safety.

Web and Digital Media Staff

The Web and Digital Media Staff support the agency during an emergency with the following activities:

- Responsible for directing the design, content management, usability, and evaluation of the FDA website (www.fda.gov). Develops and interprets the agency's Web policies and serves as advocates for FDA's Web presence and catalysts for creative use of the Web and digital media by the agency.
- Works closely, as partners, with the FDA Office of Information Management (OIM), which is responsible for the technical operations of FDA's website.
- Serves as the focal point and contact with the agency, HHS, and other Federal Government website programs and operations.
- Provides direction, strategic planning assistance, and management coordination on agency website and digital media programs.
- Works closely with the website contacts in each of the Centers and principal Offices of the Commissioner to plan, coordinate, execute, and evaluate the agency's website operations.
- Designs, develops, implements, monitors, and manages information published on the agency's website and external digital assets.

- Delivers the agency's messages to the public via the agency's website and strategic online partnerships in the Government, private, and nonprofit sectors.
- Establishes, manages, and monitors the implementation of agency standards for social media. Provides direction and strategic planning assistance related to social media.

C.1.6.1 Office of Communications

The Office of Communications supports the agency during an emergency with the following activities:

- Oversees and directs the agency's print and online communications and visual identity to ensure quality and consistency as well as coherence in decision-making and the efficient operation of these internal functions across the agency and department as a whole.
- Acts as the agency's liaison with HHS for all publications and audiovisual needs; provides pre-publication clearance of publications, exhibits, and audiovisual materials in accordance with procedures established by the agency, USPHS, HHS, the Office of Management and Budget (OMB), and the White House.
- Creates and disseminates the agency's flagship consumer health information, which includes timely and easy-to-read consumer update articles, videos, and photo slideshows containing the latest on all FDA-regulated products and practical wellness and prevention information to empower consumers. Manages the "For Consumers" section of the FDA website.
- Directs all aspects of FDA's internal communications for employees, including the content and visual strategies for the homepage of the agency's internal website; creates and coordinates agency-wide creation of content for reaching employees using a broad range of communications vehicles.
- Drafts speeches, informal remarks, talking points, slides, op-ed pieces, and letters to the editor for the Commissioner. Advises the Commissioner and other senior FDA executives on messages about FDA's public health priorities, initiatives, and crucial priorities.
- Manages speaker requests for issues that cut across FDA's organizational and product lines, as well as major meetings that involve various FDA Centers and Offices.
- Serves as a key resource for historical perspectives as well as records and resources used for agency communications and programs, including printed and online information, commemoratives, anniversaries, and milestones.

C.1.6.2 Consumer Health and Constituent Affairs

Consumer Health and Constituents Affairs support the agency during an emergency with the following activities:

- Advises the Commissioner and other key FDA officials on matters related to patients, patient advocacy, health professionals, consumers, State and Federal activities, and industry issues.
- Assists in the planning, administration, development, and evaluation of FDA policies related to patient advocacy and health professional organizations, consumers, States, and industry on serious and life-threatening issues.
- Serves as a liaison between FDA and stakeholder organizations to educate various constituents on FDA-related issues and activities.
- Provides internal coordination on FDA activities related to patient advocacy, health professional organizations, consumer groups, State organizations, and industry groups on high-priority topics such as serious and life-threatening diseases, imminent public health needs, and other special health issues.

- Coordinates and implements policies, programs, and initiatives related to MedWatch, including the MedWatch Web pages, E-list, RSS [Really Simple Syndication] feed, and Twitter account.
- Ensures patient perspectives are taken into consideration during drug development and policy issues through the patient representative and patient consultant programs. Encourages and supports active participation of these groups in forming FDA regulatory policy to ensure the agency's decisions are based upon a full range of perspectives.
- Administers MedWatch, the FDA safety information and adverse event reporting program. Also provides education and information on FDA's key responsibilities, particularly the drug approval process, clinical trial design, and expanded access to investigational therapeutic products.

C.1.6.3 Office of Media Affairs

C.1.6.3.1 Media Relations Staff

The Media Relations Staff support the agency during an emergency with the following activities:

- Advises and assists the Commissioner of Food and Drugs and other key FDA officials on all news media activities; serves as a liaison with USPHS and HHS on news media activities.
- Serves as the agency focal point for preparing, clearing, and disseminating press announcements and other statements for the news media on agency activities, as well as arranging and facilitating press conferences, media briefings, media availabilities, interviews, and other news events.
- Establishes policy for and responds to news media inquiries with timely and accurate information; coordinates and maintains liaison with news media covering FDA activities.
- Facilitates news media interviews with senior agency officials and provides guidance and appropriate training to interview subjects on advisable conduct during news media contacts.
- Analyzes media coverage, conducts assessments and evaluations of media relations tactics to ensure objectives were met, and identifies areas for improvement.
- Plans, develops, and implements agency-wide multimedia communications strategies for disseminating regulatory and educational materials to the public through the news media in support of the agency's top priorities and initiatives.
- Provides important daily newsclips about the agency to FDA employees and distributes the Daily News Media Report to HHS.
- Delegates FOIA denial authority to the Division of Freedom of Information for the agency.

C.1.7 Office of the Chief Scientist

The Office of the Chief Scientist (OCS) serves as the agency's focus for scientific, medical, and related activities within the OC. OCS provides strategic leadership, coordination, and expertise to support scientific excellence, innovation, and capacity to achieve FDA's public health mission. The Offices within OCS are as follows: the Office of Counterterrorism and Emerging Threats (OCET), Office of Critical Path Programs, and the newly established Office of Scientific Integrity (OSI) and Office of Regulatory Science and Innovation (ORSI). Additionally, the National Center for Toxicological Research (NCTR) has a direct reporting relationship to the OC and an indirect reporting relationship to OCS.

OCS also supports science and public health activities by effectively anticipating and responding to counterterrorism and emerging deliberate and natural threats (e.g., CBRN) to U.S. and global health and security, including through OCET.

C.1.7.1 Office of Counterterrorism and Emerging Threats

The OCET mission is to facilitate the development and availability of safe and effective public health emergency medical countermeasures and establish policies to safeguard medical products from adulteration and prevent disruption of supplies as a result of terrorist activities.

OCET provides strategic leadership and coordination for FDA's counterterrorism and emerging threat portfolios and works to identify and resolve complex scientific and regulatory challenges facing medical countermeasure development, approval, availability, and security. Working closely with FDA Centers, ORA, OCM, OIP, and Federal partners, OCET coordinates FDA's Medical Countermeasures Initiative (MCMi), facilitates relevant intra- and interagency counterterrorism communications, and coordinates MCMi emergency use, including EUA, activities.

OCET performs the following essential functions to support FDA's response to any threat involving use of medical countermeasures (i.e., drugs, biologics, diagnostics, and medical devices):

- Coordinate and advise senior FDA officials on the portfolio and policy of public health emergency medical countermeasures.
- Serve as the point of entry to FDA for public health emergency medical countermeasures and policy communications.
- Facilitate intra- and interagency communications on counterterrorism and emerging threats and policies related to the use of unapproved medical products or the unapproved use of approved medical products (e.g., EUA).
- Promote counterterrorism and emerging threats goals and needs in the agency priority-setting process.
- Develop and implement a comprehensive FDA strategy for counterterrorism and emerging threats.
- Provide strategic input on budget formulation as it relates to FDA's MCMi.
- Participate in the development of counterterrorism and emerging threats risk communication strategies.
- Activate and implement FDA emergency response plans as appropriate.
- Participate in the command structure for the IMG.
- Inventory human capital and determine the welfare of staff and need for reassignment of duties within the office as OCET staff shortages begin to occur.
- Prioritize and address responses to policy issues related to the ongoing crisis.
- Coordinate FDA activities for emergency use of medical countermeasures, including response to EUA requests.
- Conduct public outreach to stakeholders as appropriate.
- Develop and coordinate internal OCET planning for preparedness and response, including identifying essential functions, identifying essential personnel with adequate tiers for redundancy, and equipping essential personnel with necessary requirements to complete essential functions from decentralized worksites.

C.1.7.2 National Center for Toxicological Research

NCTR conducts FDA mission-critical scientific research to support and anticipate FDA's regulatory needs. This research is targeted to understand critical biological events in the expression of toxicity and to develop and characterize methods and incorporate new technologies to improve the assessment of human exposure, susceptibility, and risk. In an emergency or disaster, NCTR is responsible for, but not limited to, the following activities:

- Responding to RFIs from the Commissioner, other FDA Centers, and Federal Agencies.
- Providing SME consultations to support informed decision-making in responding to health-related issues associated with the incident.

C.2 OFFICE OF OPERATIONS

OO provides executive direction, leadership, coordination, and guidance for the day-to-day operations of FDA; manages overall budgets and resources; and oversees management and business activities across all FDA headquarters and field offices. OO also ensures that proper conduct of FDA's administrative and financial management activities, including budget, finance, acquisitions, IT, HR, organization, methods, and similar support activities effectively support program operations. These activities are available resources to support FDA's emergency phases. The Offices under OO that report to the Chief Operating Officer and have responsibilities related to an emergency phase are:

- Office of Business Services (OBS)
- Office of Finance, Budget, and Acquisition (OFBA)
- Office of Human Resources (OHR)
- Office of Facilities Engineering and Mission Support Services (OFEMS)
- Office of Security Operations (OSO)

In the Immediate Office, the Employee Safety and Environmental Management staff in an emergency or a disaster is responsible for, but not limited to, the following activities:

- Ensuring employees' safety prior to, during, and while recovering from an emergency event by providing guidance and available resources to staff.
- Providing subject matter expertise and leadership for radiological emergencies.

C.2.1 Office of Business Services

OBS in an emergency or a disaster is responsible for, but not limited to, the following activity:

- Ensuring effective employee administrative support through Employee Resource and Information Center (ERIC) Call Center operations.

C.2.2 Office of Finance, Budget, and Acquisition

C.2.2.1 Office of Budget

The Office of Budget (OB) is responsible for developing budget formulation plans and organizes and carries out annual and multiyear budgeting in support of the nationwide public health protection programs administered by FDA. In coordination with FDA Centers and Offices, OB responds to requests for budget information, special reports, and exhibits and provides expertise and performs all duties involved with the formulation, justification, and presentation of FDA budget submissions to HHS, OMB, and Congress. In an emergency or disaster, OB is responsible for, but not limited to, the following activities:

- Providing expert advice on and managing supplemental budget requests to support unforeseen expenses during critical periods or events; OB would facilitate this process by working with senior management and Centers to identify resource needs, implementing the process to formulate the budget request, providing essential support during the review and clearance process, and responding to questions from Congressional Appropriations staff and other stakeholders.
- Facilitating that process by conducting outreach and coordinated communications, gathering information, and communicating with senior FDA management, Centers, HHS, OMB, and Congressional Appropriations staff.

C.2.2.2 Office of Acquisitions and Grants Services

The Office of Acquisitions and Grants Services (OAGS) is responsible for negotiating, awarding, and managing all contracts, cooperative agreements, interagency agreements, grants, administration of the purchase card program for FDA, MOUs, and technology transfers. OAGS is also responsible for writing acquisition policy, providing strategic business advice and support to our stakeholders, and liaising with the HHS Senior Procurement Executive.

Administrative functions, such as payroll, travel, and timekeeping, will be provided by the Administrative Officer, Director's Administrative Assistant, and other administrative support personnel.

C.2.2.3 Office of Financial Operations

The Offices that comprise the Office of Financial Operations (OFO) plan, direct, and coordinate a comprehensive financial management operations program for FDA, encompassing the areas of budget analysis, execution, automated financial systems, fiscal accounting, internal financial audit, financial services related to accounts payable, travel support and payroll liaison, and financial reporting.

C.2.2.3.1 Office of Financial Management

The Office of Financial Management (OFM) is FDA's steward of financial assets and resources. OFM performs the following essential functions to support FDA's response to an emergency:

- **Budget Execution.** Apportions funds appropriated by Congress among components and oversees transfers of funds between components; this includes processing user fees.
- **Accounts Receivable – User Fees.** Receives user fee payments, which allows FDA's certification process to continue.
- **Financial Statements and Reports.** Prepares the agency's financial statements and maintains its general ledger.

C.2.2.3.2 Office of Financial Services

The Office of Financial Services is responsible for the following activities:

- Directs and coordinates operations for financial services related to accounts payable, travel support, and payroll liaison.
- Monthly, Quarterly, and Yearly Closing—coordinates month-end, quarter-end, and year-end close of financial operations within the Unified Financial Management System (UFMS).
- Maintains liaison with the Program Support Center (PSC) and the Defense Financial Accounting System (DFAS) representatives on issues relating to pay and leave and monitors the processes to ensure the successful payment to employees.
- When necessary during an event, the Division of Travel Services may oversee the following: processing of vouchers and traveler's reimbursements, the GovTrip system, the agency's Travel Card and Centrally Billed Account programs, and travel process for all State employees working in tandem with ORA employees.

C.2.3 Office of Information Management

OIM enables FDA's strategic efforts to transform and improve the information systems and infrastructure needed to support critical agency operations. The Office implements and enhances common systems to support FDA's regulated products. It also maximizes the availability and use of information technologies that increase or enhance electronic access for the public, as well as the full span of FDA's external and internal customer base, while maintaining effective security. OIM aligns IT investments to business goals that fully support core mission and business priorities and reduces costs of existing legacy systems. The Office consolidates, modernizes, and optimizes FDA's IT infrastructure and provides the platform required for the agency to meet IT initiatives and to move towards the bioinformatics era of science-based decisions.

In an emergency or disaster, OIM is responsible for, but not limited to, the following activities:

- Ensuring the command and control of all reporting to OIM.
- Ensuring data centers (there are four main data centers) are functioning and coordinating with the appropriate building management to determine the building status.
- Ensuring IT security services are available that are essential to protect FDA's IT assets and identifying and applying patches that will address the most critical security vulnerabilities.
- Ensuring the availability of FDA local area network (LAN)/wide area network (WAN) that will be critical for both field and local users to access agency IT resources.
- Maintaining Internet services that are critical to the agency's ability to communicate with regulated industry and providing access to FDA's internal and external IT resources.
- Ensuring Active Directory availability to provide authentication services when users log onto FDA systems.
- Ensuring telephone availability, Voice over Internet Protocol (VoIP) customer support, and continuity of agency email/BlackBerry services.
- Monitoring the availability of agency Outlook Web Access (OWA).
- Managing and maintaining IT help desk and application support services.
- Ensuring a Special Routing Arrangement Service infrastructure that will support 16,000 concurrent broadband users and approximately 350 dial-in users.
- Ensuring FDA staff can perform non-standard queries and data extractions.
- Ensuring agency computer application and file/print services.
- Monitoring and maintaining the availability of applications and databases.
- Procuring additional contract services or information system hardware/software components as appropriate.

C.2.4 Office of Human Resources

In an emergency or disaster, OHR is responsible for, but not limited to, the following activities:

- Reviewing employee issues related to telework, leave, flexiplace, social distancing, and other HR issues; assessing the impacts of related decisions, such as building closures; issuing clear guidance consistent with the Office of Personnel Management (OPM), HHS, and other administration directives and policies while integrating program priorities and mission requirements; and maintaining a clear line of communication on both an agency and individual level so that the implementation of policies is consistent and well understood across FDA.
- Coordinating and liaising with the FDA Office of Financial Services to ensure OHR employees adhere to any timekeeping updates necessary to continue receiving compensation.
- Providing coordination between FDA management and the Assistant Secretary for Health's Commissioned Corps programs; serving the FDA Centers, special assignments, and details to other organizations and initiatives.
- Providing leadership and direction regarding all aspects of agency-wide HR management.
- Ensuring internal and external customer services continue to be provided.

C.2.5 Office of Facilities Engineering and Mission Support Services

In an emergency or disaster, OFEMS is responsible for, but not limited to, the following activities:

- Ensuring FDA facilities are safe and available for staff and acquiring temporary facilities if necessary.
- Providing direct interface with the U.S. General Services Administration (GSA) for services in all leased facilities.

C.2.6 Office of Security Operations

OSO has responsibility for agency-wide physical and personnel security programs, including the suitability and National Security Information program. In an emergency or disaster, OSO is responsible for, but not limited to, the following activities:

- Ensuring the national security clearances of personnel assigned to various EOCs as part of a response are either sent to or received by the appropriate EOC.
- Providing guidance on the proper handling, marking, processing, and storage of classified materials.
- Coordinating agency COOP activities, which address how to continue agency operations when the availability of FDA facilities to accomplish agency work has been impacted by an emergency.
- Ensuring the physical security of all nationwide FDA facilities; the Physical Security Branch may coordinate with on-duty security guard personnel regarding any temporary staff deployment issues that may arise during an emergency.

C.3 OFFICE OF FOODS AND VETERINARY MEDICINE

The FDA Foods and Veterinary Medicine (FVM) Program includes CFSAN and CVM, along with the food-related activities of ORA and the CORE Network and draws on the resources and expertise of FDA's NCTR and key OC staff Offices.

OFVM provides executive leadership and strategic direction to the FVM Programs to protect and promote the health of humans and animals by ensuring the safety of the American food supply, food additives, and dietary supplements as well as the safety of animal feed and the safety and effectiveness of animal drugs. The FVM Program does this by setting science-based standards for preventing food and feedborne illnesses and ensuring compliance with these standards; protecting the food and feed supply from intentional contamination; and ensuring that food labels contain reliable information and encouraging product reformulation to allow consumers to make healthy choices and promote well-being. OFVM is also responsible for leading FDA's efforts in responding to foodborne outbreaks and contamination. The FVM Program leads the implementation of the FDA FSMA. The FVM Program also promotes and protects the health of humans and animals by regulating the manufacture and distribution of food additives and drugs that will be given to animals.

The FDA FVM Program protects and promotes the health of humans and animals by:

- Posting vital and important information, emergency messages, and other communication information quickly to users via the FDA website, in coordination with OEA.
- Ensuring the safety of foods for humans, including dietary supplements.
- Ensuring the safety of animal feed and the safety and effectiveness of animal drugs.
- Setting science-based standards for preventing foodborne illness and ensuring compliance with these standards.
- Coordinating foodborne outbreak surveillance, response, and post-response activities related to incidents involving multiple illnesses linked to FDA-regulated human and animal food and cosmetic products.
- Protecting the food and feed supply from intentional contamination.
- Ensuring that food labels contain reliable information consumers can use to choose a healthy diet.

C.3.1 Coordinated Outbreak Response and Evaluation Network

The CORE Network is responsible for coordinating foodborne outbreak surveillance, response, and post-response activities related to incidents involving multiple illnesses linked to FDA-regulated human and animal food and cosmetic products. Members of the CORE Network at the FDA headquarters level are assigned on a continuous, full-time basis to multidisciplinary teams that coordinate efforts internally within FDA, including CFSAN, CVM, ORA, and OFVM, as well as with external stakeholders, including the CDC, USDA, and State and local health, agriculture, and regulatory agencies. The network is led by the OFVM Chief Medical Officer (CMO)/Director of CORE, who has the overall responsibility for leadership and management of FDA's activities related to incidents of illness linked to human and animal food and serves as the spokesperson during outbreaks.

CORE Network leadership includes a Deputy Director, who participates fully with the CMO in providing the leadership, policy development, decision-making, and strategic planning for food-related outbreaks and food safety issues affecting the public health within the purview of FDA. Additionally, two managers oversee the areas of Prevention (includes the Signals and Surveillance and Post-Response) and three Response Teams. Also included in the network are key strategic FDA resources in both the field and at FDA headquarters (the District Offices and Regional Specialists, the Rapid Response Teams [RRTs] that

work with State partners; FDA's OEA; the SMEs at CFSAN and CVM; and others as appropriate). In specific instances, the CORE Network will work with OCM to determine whether an IMG should be activated if the response capacity of CORE is exceeded.

In specific incidents, OCM/OEO will be immediately notified if the size, severity, and/or scope of the response to an incident is above the capacity of CORE. In this case, CORE will request the assistance of the EOC to activate an IMG to coordinate the response to the incident consistent with the FDA EOP.

C.3.2 Center for Food Safety and Applied Nutrition

CFSAN, in conjunction with the agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the Nation's food supply is safe, sanitary, wholesome, and honestly labeled and that cosmetic products are safe and labeled properly. CFSAN has the authority to regulate establishments that manufacture, process, pack, hold, or grow food involved in interstate commerce, including manufacturers, distributors, and warehouses. It also determines whether data collected by another agency or organization are adequate for FDA decisions regarding food and cosmetic issues. In an emergency or disaster, CFSAN is responsible for, but not limited to, the following activities:

- Collaborating with other public health agencies and industry regarding food contaminants and other monitoring programs for foodborne illness programs.
- Providing critical information on food safety, food defense, and regulatory issues to consumers, industry, and other Federal and SLTT governmental and international entities (all levels of the food chain).
- Protecting human health through regulatory, legal, and administrative actions.
- Participating actively in legal proceedings critical to the safety and defense of the food supply.
- Using import alerts to prevent unsafe food and cosmetic products from entering the United States.
- Facilitating coordination of food contamination investigations between FDA and the States.
- Identifying foods that are at elevated risk of contamination and investigating the effectiveness of food processing and preparation practices.
- Developing and disseminating recommendations on measures to prevent the contamination of FDA-regulated foods and cosmetics.
- Developing and evaluating analytical methods for identifying food and cosmetic contaminants.
- Critically reviewing cases and other regulatory actions sent from the Office of Compliance to evaluate whether proposed regulatory action is supported by findings and providing policy and technical input to FDA field investigations.
- Identifying and training a cadre of CFSAN personnel for potential rapid deployment to the FDA EOC, to HHS, and to external organizations to provide support for contingency functions.

C.3.3 Center for Veterinary Medicine

CVM ensures the safety, efficacy, and quality of drugs for animals (including food-producing and companion animals), animal food and feed, and medical devices used on animals potentially threatened by an incident. In an emergency or disaster, CVM is responsible for, but not limited to, the following activities:

- Protecting animal and human health through regulatory, legal, and administrative actions.
- Actively participating in legal proceedings critical to the safety of the food and feed supply.
- Using import alerts to prevent unsafe products from entering the United States.
- Facilitating coordination of meat and milk residue investigations between FDA and the States.
- Providing sponsors and other stakeholders with guidance on the use of animal drugs that serve as potential medical countermeasures in animals.
- Providing information on critical safety and regulatory issues to stakeholders, consumers, industry, veterinarians, and other Government officials.
- Collaborating with public health agencies regarding feed contaminant, tissue residue programs, and other monitoring programs for meat and poultry products.
- Providing information regarding manufacturers' compliance with Good Manufacturing Practices (GMPs) and other relevant animal drug product quality issues.
- Providing technical advice and assistance in the assessment of animal drug or feed product possibly affected.
- Assessing the availability, production capacity, and surge capacity of animal drugs and providing information on alternative sources of critical products in shortage situations.
- Providing an assessment on the diversion of contaminated human food for animal feed use.
- Providing advice to pet owners regarding animal safety measures.

C.4 OFFICE OF MEDICAL PRODUCTS AND TOBACCO

OMPT provides executive leadership, management, and policy direction to all FDA medical product- and tobacco-related programs. The Office exercises, on behalf of the Commissioner, direct line authority over CDER, CBER, CDRH, and the Center for Tobacco Products (CTP). The Office directs the activities of FDA's special medical programs, including OCP, the Office of Orphan Products Development, the Office of Good Clinical Practice (OGCP), and the Office of Pediatric Therapeutics (OPT). The Office directs efforts to integrate the programs, as necessary, of CDER, CBER, CDRH, and CTP, and thereby ensure the optimal use of all available FDA resources and tools to improve the safety and proper labeling of medical products and tobacco. The Office is responsible for the following activities:

- Directs the development of integrated strategies, plans, policies, and budgets to build FDA's medical product- and tobacco-related scientific and regulatory capacities and programs, including recruitment and training of key personnel and development of information systems.
- Represents FDA on medical product- and tobacco-related matters in dealing with the Office of the Secretary of HHS, the White House, other elements of the Executive Branch, and with Congress.
- In conjunction with the Deputy Commissioner for Global Regulatory Operations and Policy, represents FDA on medical product- and tobacco-related matters in dealing with foreign governments and international organizations.
- Directs FDA efforts to build consistency and uniformity in the evaluation for safety and efficacy of new medical products and new tobacco products.

C.4.1 Office of Special Medical Programs

The Office of Special Medical Programs (OSMP) Immediate Office oversees and coordinates the program offices that comprise OSMP. The OSMP Immediate Office:

- Provides leadership and direction in the coordination of internal and external review of pediatric science, safety, ethics, and international issues in accordance with laws and regulations.
- Oversees the implementation of the Orphan Products provisions of the FD&C Act to encourage the development of drugs of limited commercial value for use in rare diseases and conditions to promote the public health; the Immediate Office provides leadership in developing and communicating agency policy on orphan product activities, including protocol assistance, designation, exclusivity, and grants and contracts.
- Provides leadership and direction on Good Clinical Practice (GCP) and HSP regulation, policy, harmonization, and outreach activities; the Immediate Office oversees development of regulations and policy to help ensure protection of human subjects involved in FDA-regulated research and the integrity of data resulting from such trials.
- Provides leadership and direction on issues involving the regulation of combination products, the classification of human medical products, and jurisdiction over human medical products; the Immediate Office oversees development of regulations, policy, procedures, and processes to facilitate classification of human medical products and the agency's regulation, review, and oversight of combination products.
- Provides leadership in management and oversight of FDA Advisory Committees to provide consistent application of laws and policies applicable to such committees; the Immediate Office oversees development of policy, procedures, and processes to maintain and improve the agency's Advisory Committee program.

- Evaluates and responds to appeals involving product classification decisions, assignment of combination product decisions, and orphan product designations.

C.4.1.1 Office of Good Clinical Practice

In general, the mission of the OGCP focuses on longer term policy/regulation development and intra-agency coordination of issues related to the conduct of clinical trials and the protection of the rights, safety, and welfare of subjects in FDA-regulated studies. There are, however, several mission-critical areas for which OGCP is responsible that require daily attention and that may have heightened importance during an emergency situation, particularly an emergency that directly impacts the conduct of ongoing clinical trials. These areas include addressing clinical trial/HSP inquiries, questions related to emergency or compassionate use of investigational articles, trial-specific concerns, EUAs, and coordination of interagency GCP/HSP issues. Should the emergency situation have a major impact on the conduct of clinical trials in one or more areas of the country, OGCP could potentially establish an emergency-specific hotline, as was done in the aftermath of Hurricane Katrina. Major concerns regarding subject safety could include identification of an accessible clinical site(s) for continued subject care depending on the specific situation.

C.4.1.2 Office of Combination Products

OCP ensures the prompt assignment of combination products to FDA Centers, the timely and effective pre-market review of such products, and consistent and appropriate post-market regulation of like products subject to the same statutory requirements to the extent permitted by law. In addition, OCP is responsible for determining whether articles are drugs, devices, biological products, or combination products if their classification is unclear or in dispute. In an emergency or disaster, OCP is responsible for, but not limited to, the following activities:

- Classifying articles as drugs, devices, biological products, or combination products.
- Assigning an FDA Center to have primary jurisdiction for review of a combination product.
- Ensuring consistency and appropriateness of post-market regulation of combination products.
- Updating agreements, guidance documents, or practices specific to the assignment of combination products during the incident.
- Working with FDA Centers to implement guidance or regulations to clarify the agency regulation of combination products.
- Serving as a focal point for combination products issues for internal and external stakeholders.

C.4.1.3 Office of Orphan Products Development

The Office of Orphan Products Development develops and communicates agency policy and makes decisions on approval of sponsor requests and incentives, including orphan product protocol assistance, orphan product designation, orphan product exclusivity, and orphan product grants and contracts, to support clinical research and other areas of agency policy related to the development of products for rare disorders. It reviews IND and biologics applications and IDEs to locate the existence of products under investigational study that show promise for effectiveness for rare or common diseases but lack commercial sponsorship. It assists sponsors, researchers, and investigators in communicating with agency regulatory officials and expediting solutions to problems in obtaining investigational exemptions or pre-market approval status.

C.4.1.4 Office of Pediatric Therapeutics

OPT coordinates and facilitates all activities of FDA that may have any affect on a pediatric population or the practice of pediatrics or may in any other way involve pediatric issues. In an emergency or disaster, OPT is responsible for, but not limited to, the following activities:

- In direct coordination with CDER's Office of Surveillance and Epidemiology and CDER's Pediatric and Maternal staff (within the Office of New Drugs), and in consultation with CDER's Office of Counterterrorism and Emergency Coordination, review and address all adverse event reporting involving drugs used in the pediatric population.
- In direct coordination with CDRH's Pediatric Steering Committee and Medical Product Surveillance Network (MedSun), address emergency issues related to device use in pediatrics.
- Provide consultation and coordination on pediatric issues across Centers and with external groups and agencies as well as provide representation on groups such as the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) working group.

C.4.1.5 Advisory Committee Oversight and Management Staff

The Advisory Committee Oversight and Management Staff (ACOMS) coordinates and facilitates all activities of FDA that are related to the establishment and operations of FDA's Advisory Committees. ACOMS is responsible for seeing that all statutory and regulatory requirements and agency policies are met when conducting all Advisory Committee meetings, including the screening of members for potential financial conflicts of interests. In an emergency or disaster, ACOMS is responsible for the following activities, among others:

- Overseeing the operations of the Centers to obtain the appropriate experts to attend a meeting.
- Assisting the Centers, if necessary, in procuring a space to hold the meeting.
- Assisting the Centers, the Regulations Policy Management staff, and the Associate Commissioner for Special Medical Programs in publishing public meeting announcements in the *Federal Register* and on the FDA website.
- Reviewing the financial interests of all individuals invited to participate in the meeting for potential financial conflicts of interest. (This is conducted with the assistance of the Centers, the Ethics and Integrity staff, and the Associate Commissioner for Special Medical Programs. If any members require waivers to participate, ACOMS coordinates disclosure with the Division of Freedom of Information and the FDA Web staff.)

C.4.2 Center for Drug Evaluation and Research

CDER ensures the safety, efficacy, and quality of drugs (including prescription and over-the-counter drugs, both brand name and generic) and therapeutic biological agents for use as medical countermeasures. In an emergency or disaster, CDER is responsible for, but not limited to, the following activities:

- Providing sponsors and other stakeholders with regulatory guidance on the development and use of medical countermeasures against CBRNE agents or emerging infectious threats (e.g., severe acute respiratory syndrome [SARS] and 2009 H1N1 [swine flu]) when there is no FDA approval for the product or proposed indication or when another issue would cause the product to be considered adulterated or misbranded.
- Facilitating communications with manufacturers on adverse event reporting during an emergency.

- Collaborating with public health agencies regarding drug and therapeutic biologic product stockpile issues, including labeling, appropriate usage, product performance, monitoring, use in special populations, product expiry (e.g., the Shelf Life Extension Program), and other evolving issues.
- Processing EUA requests for drugs and therapeutic biologic agents after a public health emergency is declared by the Secretary.
- Providing information to manufacturers regarding compliance with GMP and other relevant product quality issues, including extension of product expiry.
- Assessing the availability, production capacity, and surge capacity of drugs and therapeutic biologic products used as countermeasures and providing information on alternative sources of critical medical countermeasures in shortage situations.
- Managing CDER laboratory capabilities.
- Monitoring media and marketplace for counterfeit or violative drugs (or advertising) of particular relevance to the emergency.
- Enhanced monitoring and evaluation of adverse events associated with products relevant to the emergency.
- Reviewing public communications related to CDER-regulated products relevant to the emergency.

C.4.3 Center for Biologics Evaluation and Research

CBER ensures the safety, efficacy, and quality of biological products (including blood and blood products, vaccines, tissues, and cellular and gene therapies) potentially used as medical countermeasures. In an emergency or disaster, CBER is responsible for, but not limited to, the following activities:

- Providing sponsors and other stakeholders with guidance on the use of biological products as medical countermeasures.
- Using sound science and regulatory expertise to review, evaluate, and license new biological products that are safe, effective, and of high-quality standards.
- Facilitating the availability of safe and effective vaccines, blood and blood products, cells, tissues, gene-therapies, devices, and other biological products used to prevent and treat disease outbreaks.
- Collaborating with public health agencies regarding biologics stockpiling issues, including labeling, appropriate usage, product performance, monitoring, use in special populations, and other evolving issues.
- Ensuring compliance with current GMP for all regulated manufacturers.
- Providing regulatory guidance on the use of unapproved products or unapproved uses of approved products.
- Processing EUA requests for biological products after a public health emergency is declared by the Secretary.
- Providing information regarding manufacturers' compliance with current GMP and other relevant product quality issues.
- Assisting in the assessment of potentially contaminated biological products.
- Assessing the availability, production capacity, and surge capacity for biologic products used as medical countermeasures and providing information on alternative sources of critical medical countermeasures in shortage situations.

- Managing CBER laboratory testing and lot release capabilities.
- Communicating information, including risk information, about biological products to industry, consumers, SLTT governments, and other stakeholders.
- Conducting post-marketing surveillance and enforcement activities relating to biological products.

C.4.4 Center for Devices and Radiological Health

CDRH ensures the safety, efficacy, and quality of medical devices, including IVD and radiological products. In an emergency or disaster, CDRH is responsible for, but not limited to, the following activities:

- Processing EUA requests for medical devices (i.e., diagnostics, personal protective equipment [PPE], and radiological products) after a public health emergency is declared by the Secretary.
- Facilitating the development, regulatory review, and production of diagnostic devices, PPE, and other devices that may be needed.
- Conducting post-market surveillance to monitor the safety and effectiveness of devices used, including for diagnosis, therapeutics, PPE, and supportive care.
- Supporting efforts to ensure an adequate supply of devices through cooperative interactions with manufacturers and distributors and coordination with the Strategic National Stockpile (SNS) to determine the adequacy of stocks and actions required to meet targeted amounts.
- Using an emergency shortages database to identify and monitor supplies of certain devices that are or have the potential to be in demand.
- Educating device users on how to use devices in a safe and effective manner.
- Collaborating with public health agencies regarding product stockpile issues, appropriate usage, labeling, product performance, monitoring, use in special populations, and other evolving issues.
- Communicating information, including risk information, about medical devices and radiation-emitting products to industry, consumers, SLTT governments, and other stakeholders.

C.4.5 Center for Tobacco Products

CTP is responsible for protecting the public's health by restricting the marketing and access of tobacco products to minors; regulating the manufacturing, distribution, and labeling of tobacco products; setting tobacco products standards; requiring registration of tobacco manufacturers; and requiring ingredient and constituent listings for tobacco products. In an emergency or disaster, CTP is responsible for, but not limited to, the following activities:

- Collaborating with other public health agencies to communicate information regarding tobacco product contaminants and to coordinate monitoring for patterns of exposure and illness.
- Protecting human health through regulatory, legal, and administrative actions.
- Participating actively in legal proceedings critical to ensuring compliance with tobacco product regulatory standards.
- Facilitating coordination of tobacco product contamination investigations between FDA and SLTT governmental and international entities.
- Identifying tobacco products that are at elevated risk of contamination and investigating the effectiveness of tobacco processing and preparation practices.



- Developing and disseminating recommendations on measures to prevent the contamination of tobacco products.
- Developing and evaluating analytical methods for identifying tobacco product contaminants.
- Critically reviewing cases and other regulatory actions sent from the Office of Compliance to evaluate whether proposed regulatory action is supported by findings and providing policy and technical input to FDA field investigations.
- Enhanced monitoring and evaluation of adverse events associated with products relevant to the emergency.
- Communicating information, including risk information, about tobacco products to industry, consumers, SLTT governments, and other stakeholders.
- Ordering a stop to the distribution of a tobacco product and recalling a tobacco product relevant to the emergency.

C.5 OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

OGROP provides executive oversight, strategic leadership, and policy direction to FDA's domestic and international product quality and safety efforts, including global collaboration, global data-sharing, development and harmonization of standards, field operations, compliance, and enforcement activities. GROOP is responsible for the following activities:

- Drives improvement in FDA's risk analytics and IT capability, in conjunction with OIM, to enhance FDA's gathering and use of intelligence in directing its regulatory efforts.
- Leverages public and private sector third parties to increase FDA's global knowledge and coverage.
- Convenes and chairs a Global Programs Board consisting of the ACRA, the Directors of all FDA product Centers, and other agency leaders to coordinate and enhance FDA's global efforts.
- Provides executive leadership and management to all programs in ORA and OIP.
- Exercises, on behalf of the Commissioner, direct line authority over ORA and OIP.
- Exercises, on behalf of the Commissioner, all international and ORA-related legal authorities that the Commissioner is empowered to exercise under the FD&C Act, as amended; the PHSA; and other applicable laws.
- Represents FDA on matters relating to domestic and international product quality and safety efforts in dealings with the Executive Branch, Congress, foreign governments and international organizations, and others.

C.5.1 Office of International Programs

OIP serves as the agency focal point for international issues. The Office leads, manages, and coordinates all of FDA's international activities to effect an affirmative and strategic public health agenda in the international area; enhance and maximize FDA's communications and interactions globally, ensuring they reflect the agency's policies and best scientific, legal, and policy thinking; ensure that FDA international communications and interaction are consistent with HHS public health objectives; and leverage resources with counterpart foreign agencies and international organizations in meeting FDA's public health mission. In an emergency or disaster, OIP is responsible for, but not limited to, the following activities:

- Coordinating FDA communications with DOS, including U.S. embassies abroad, foreign governments, and international organizations, including foreign embassies and consulates in the United States.
- Exchanging information, and advising on clearing such, with foreign counterparts and other international partners to ensure compliance with laws and policies and consistency in responses.
- Assessing in real-time and in-country, where possible, the conditions and events in those areas that might have an impact on the safety, quality, and availability of FDA-regulated products exported to the United States.
- Engaging more proactively and consistently with various international communities in strategic regions abroad, including foreign governments, foreign regulatory counterparts, international organizations, other U.S. Government colleagues working abroad, industry, and the academia/research community; such engagements are intended to help FDA better accomplish its mission to collaborate with foreign regulatory authorities to reduce regulatory burdens, harmonize regulatory requirements, and establish appropriate reciprocal arrangements in order to promote and protect the public health of the United States by obtaining better information to help FDA Centers, ORA, and OC make better informed regulatory and other decisions.

- Managing formal arrangements with foreign governments (e.g., MOUs, mutual recognition agreements, exchange of letters, confidentiality commitments) to facilitate rapid and efficient information exchange and other cooperation.
- Facilitating international technical cooperation and assistance activities and capacity building for emergency collaborations.
- Implementing policies and procedures pertaining to emergency international travel and processing international travel requests.
- Facilitating international visitors as needed.

C.5.2 Office of Regulatory Affairs

ORA protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products. ORA is led by the ACRA and is the lead Office for all agency field activities. ORA is composed of: Resource Management, Criminal Investigations, Communications and Quality Program Management, Partnerships, Policy and Risk Management, and Operations (which includes four headquarters, five Regional, and 20 District offices); a Senior Advisor; and a Deputy ACRA (DACRA). In an emergency or disaster, ORA's responsibilities include, but are not limited to, the following activities:

- Coordinating, interpreting, and evaluating the agency's overall compliance efforts.
- Providing advice or assistance to the Commissioner and other key officials on regulations and compliance-oriented matters related to the incident.
- Stimulating awareness within the agency of the need for prompt and positive action to ensure compliance by regulated industries.
- Working to ensure an effective and uniform balance between voluntary and regulatory compliance and agency responsiveness to consumer needs.
- Evaluating and coordinating all proposed legal actions to ascertain compliance with incident-related regulatory policy and enforcement objectives.
- Executing direct line authority over all agency field operations; developing, issuing, approving, or clearing proposals and instructions affecting field activities; and serving as the central point within the agency through which headquarters offices obtain emergency field support services.
- Providing direction and counsel to RFDDs in the implementation of policies and operational guidelines that form the framework for emergency management of agency field activities.
- Developing and/or recommending to the Commissioner emergency policy, programs, and plans for activities between the agency and State and local governments.
- Administering the agency's overall Federal-State program and policy and coordinating the program aspects of agency contracts with State and local counterpart agencies.
- Evaluating the overall management and capabilities of the agency's field organization and initiating action to improve the management of incident-related field activities.

C.5.2.1 Deputy Associate Commissioner for Regulatory Affairs

C.5.2.1.1 Office of Communications and Quality Program Management

The Office of Communication and Quality Program Management (OCQPM) is responsible for providing leadership, coordination, and management of the ACRA priority policies and issues impacting ORA and agency operations. Identifies triages, supervises, and tracks related actions from start to finish in conjunction with senior leadership across ORA.

- The Internal Communications staff will establish an internal communications program, which will develop and implement ORA-wide internal communications strategies to engage and inform staff.
- The Project Coordination staff will manage critical projects across ORA.
- The Quality Management staff will continue to ensure our products, processes, procedures, and systems continually improve, strengthening our overall operation and effectiveness.

C.5.2.1.2 Office of Policy and Risk Management

The Office of Policy and Risk Management (OPRM), led by the Assistant Commissioner for Compliance Policy (ACCP), has the primary responsibility for advancing ORA's goal to be strategic and to fully integrate risk management and data analysis into all policy and resource utilization decisions by:

- Serving as the ORA focal point on significant policy issues that affect ORA programs and provides coordination, development, and direction on such issues.
- Serving as the focal point for testimony requests, information disclosure requests (including those under 21 CFR 20.85, 21 CFR 20.88, and 21 CFR 20.89), and MOUs.
- Conducting risk analysis in support of policy development and work planning and to support the establishment of priorities for inspection, analysis, and compliance actions.
- Establishing and maintaining the ORA work plan in alignment with strategic and risk-based policy decisions.

C.5.2.1.3 Office of Partnerships

The Office of Partnerships (OP) is responsible for maintaining FDA's rapid communication systems that interface with SLTT governments, major municipalities, other Federal partners, and national public health/regulatory associations. The OP works collaboratively with State partners on contract inspection programs and implementation of the Manufactured Food Regulatory Program Standards (MFRPS) as well as cooperative agreements designed to build capability and capacity. The OP also manages the processes necessary to expedite information sharing through the issuance of commissions or other types of information sharing agreements that allow the agency to rapidly share non-public information with State and local partners. Emergency broadcast messages and 50-State conference calls are two examples of ways that information is disseminated from OP to stakeholders.

OP sponsors and provides programmatic/administrative oversight to several funded cooperative agreement programs and grants. This support strengthens State and local food regulatory agency infrastructure and enhances our partners' abilities to effectively respond to emergencies/incidents involving food or feed. Several of these programs, such as the RRT program, involve OP working in collaboration with relevant offices within ORA and OFVM to provide technical guidance and oversight and ensure the programs align with agency policy.

OP may provide personnel in response to an incident to assist in the facilitation of communications with State and local partners. Staff members will be made available around the clock to notify and provide stakeholders with essential and relevant information. If a formal agency response structure such as the

IMG is established, OP personnel are generally assigned to the FDA JIC and perform duties as described in *Section D.2.1.4.6*, “State and Local Communications Group” and *Section E.2.2*, “Communicating with States, Territories, Tribal Nations, and Local Governments.” OP personnel may also be assigned to the General Staff section, such as Operations, as dictated by the incident response.

C.5.2.2 Office of Resource Management

The Office of Resource Management (ORM) provides leadership and direction to the ACRA, DACRA, and other senior managers and staff on all areas of management, including budget formulation and execution, financial management, management analysis, personnel, facilities, and administrative operations. In an emergency or disaster, ORM is responsible for, but not limited to, the following activities:

- Advising the ACRA, DACRA, Assistant Commissioner for Operations (ACO), and RFDDs on all areas of field office administrative management—including financial management, management analysis, and administrative operations.
- Oversees the management of acquisitions and contracts within ORA.
- Adjusting overall field manpower allocations based on incident requirements.

C.5.2.3 Office of Criminal Investigations

The Office of Criminal Investigations (OCI) has primary responsibility for all criminal investigations conducted by FDA, including suspected tampering incidents and counterfeit products.²⁸ Additionally, OCI is the primary POC for all law enforcement and intelligence issues pertaining to threats or perceived threats against FDA-regulated products. OCI has special agents at FDA headquarters and in field offices nationwide. OCI also maintains a full-time presence at the National Counterterrorism Center (NCTC), the FBI’s National Joint Terrorism Task Force (NJTTF), and DHS. In case of an emergency or disaster, OCI is responsible for, but not limited to, the following activities:

- Advising and assisting the ACRA and other key FDA officials on regulations, criminal, counter-terrorism, and intelligence matters.
- Maintaining classified electronic connectivity with the U.S. Intelligence Community.
- Directing FDA criminal investigation activities in coordination with other agency components and Federal, State, and local law enforcement agencies.
- Implementing and enforcing agency policy related to criminal investigations.
- Initiating and conducting criminal investigations under all statutes administered by FDA.
- Coordinating assignments and activities involving undercover and surveillance personnel located in field offices throughout the United States.
- Ensuring coordination of criminal investigation activities with FDA Regional and District offices and adherence to the agency’s enforcement priorities through cooperative relationships with field and headquarters organizational components.
- Providing recommendations to OCC on referrals of criminal cases to DOJ, or directly to the U.S. Attorney when such direct reference is authorized, for further investigation and/or prosecution.
- Maintaining automated data processing systems to be used for criminal investigations and related enforcement matters.
- Participating in Grand Jury investigations and serving as agents of the Grand Jury.

²⁸ Any deliberate contamination of an FDA-regulated product is a criminal act under Title 18 of the U.S.C. Section 1365 (Tampering with Consumer Products).

C.5.2.4 Office of Operations

OO coordinates and manages all agency field operations, including the: Office of Enforcement and Import Operations (OEIO), Office of Food and Feed Operations (OFFO), Office of Medical Products and Tobacco Operations (OMPTO), Office of Regulatory Science (ORS), and ORA Regions. Any part of agency field operations may be called upon to respond to an emergency. OO develops issues, approves and clears proposals and instructions affecting field and import activities, and serves as the central point within the agency through which headquarters offices obtain field support services. The OO offices and their divisions working together with the field handle FDA's day-to-day and emergency operations at five Regional offices, 20 District offices, more than 165 resident posts, and 13 field laboratories.

OFFO, OMPTO, and OEIO handle enforcement actions and coordinate emergency domestic and foreign field investigations, and they are responsible for compliance systems, reflecting a global approach to emergency operations when necessary.

C.5.2.4.1 Office of Enforcement and Import Operations

OEIO advises and provides assistance on regulations and compliance matters that impact policy development, implementation, and long-range goals. OEIO coordinates, interprets, and evaluates FDA's overall compliance efforts within the United States and internationally. This Office acts as liaison with other Federal Agencies and international organizations and governments on compliance matters, evaluates proposed legal actions, coordinates these actions with OO and OCC, and handles appeals of proposed compliance actions that are disapproved by the Centers or OCC. The Division of Import Operations is located within OEIO and has responsibilities, which include, but are not limited to, monitoring and controlling import and export activity associated with implicated product(s), countries, foreign manufacturers and shippers, filers, importers, and/or consignees and coordinating targeted surveillance of imported products with the U.S. Customs and Border Protection (CBP).

In an emergency, OEIO is responsible for, but not limited to, the following activities:

- Developing compliance strategy and recommending such to the ACRA.
- Serving as FDA's focal point for guidance on recall plans and procedures.
- Directing and coordinating field activities in support of all product recalls.
- Maintaining liaison with other FDA components, industry, and other government agencies to ensure proper implementation and completion of recall plans and activities.
- Coordinating multiple District or Center enforcement actions against individuals and companies that violate the FD&C Act.
- Identifying unapproved, fraudulent, harmful, or ineffective FDA-regulated health products and initiating investigations, advisory or enforcement actions, and outreach activities when appropriate.
- Serving as the FDA focal point for activities relating to the Federal Medical Products Quality Assurance Program and maintaining liaison with other government agencies procuring medical supplies.
- Issuing final administrative approval for quality assurance of specific products/firms.

C.5.2.4.2 Office of Food and Feed Operations

OFFO represents and makes decisions on behalf of the ACO relative to food/feed program investigatory operations, including emergency response activities and international affairs. OFFO coordinates and manages all domestic and foreign field investigatory operations related to foods and feed regulated by the agency on behalf of the ACO; serves as the central point within the agency through which directorates and other headquarters offices obtain field support services for food and feed activities; and serves as the agency focal point in coordinating, directing, and assisting the field and headquarters offices with investigative food and feed activities. OFFO is comprised of the Division of Food and Feed Program Operations Branch and the Division of Food Defense Targeting (DFDT). DFDT is responsible for, but not limited to, security monitoring of shipments of food for potential contamination with CBRN agents, identifying shipments with potential terrorist connections, and coordinating specific actions against suspect shipments with FDA field personnel, OCI, and DHS CBP.

In an emergency, OFFO is responsible for, but not limited to, the following activities:

- Developing compliance policy and recommending policy to the ACRA.
- Serving as FDA's focal point for guidance on recall plans and procedures.
- Directing and coordinating field activities in support of all food and animal feed facility investigations and inspections.
- Maintaining liaison with other FDA components, industry, and other Government agencies to ensure proper implementation and completion of assessment and investigation of regulated industry, impacted food facilities, and food products.
- Coordinating multiple District or Center food and animal feed inspection and investigation activities, which are regulated under the FD&C Act.

C.5.2.4.3 Office of Medical Products and Tobacco Operations

OMPTO represents and makes decisions on behalf of the ACO relative to medical products and tobacco programs investigatory operations, including emergency response activities and international affairs. OMPTO is comprised of the Division of Medical Products and Tobacco Program Operations (DMPTPO) and the Division of Medical Products and Tobacco Inspections (DMPTI). OMPTO coordinates and manages all domestic and foreign agency field investigations operations related to medical tobacco products regulated by the agency on behalf of the ACO; serves as the central point within FDA through which the directorates and other headquarters offices obtain field support services for medical device and tobacco activities; serves as the agency focal point for coordinating, directing, and assisting the field and headquarters with investigative medical products and tobacco activities; provides inspectional and technical assistance to FDA field offices as needed; and serves as the operational liaison for medical products and tobacco inspection programs to FDA's foreign offices.

In an emergency, OMPTO is responsible for, but not limited to, the following activities:

- Recommending policy to the ACRA.
- Developing, recommending, and reviewing guidance on investigatory procedures related to medical products and tobacco.
- Directing and coordinating field activities in support of all medical products and tobacco facility investigations and inspections.
- Coordinating multiple District inspection and investigation activities and serving as liaison with other FDA components.

C.5.2.4.4 Office of Regulatory Science

ORS represents and makes decisions on behalf of the ACO relative to both food/feed programs and medical products and tobacco programs' scientific operations, including emergency response activities and international affairs. ORS is a focal point for all aspects of ORA field laboratories and serves as ORA's headquarters office responsible for scientific and technical staff related to foods and feed and medical tobacco products regulated by the agency.

In an emergency, ORS is responsible for, but not limited to, the following activities:

- Preparing ORA laboratory response and monitoring surveillance databases.
- Activating the Food Emergency Response Network (FERN).
- Developing, recommending, and reviewing guidance on laboratory procedures.
- Coordinating ORA laboratory response.

C.5.2.4.5 ORA Regions and Districts

FDA's field organization is divided into Regional and District offices responsible for performing inspections, sample collections, and analyses of both domestic and imported products; responding to local emergencies; and initiating enforcement actions for all of the agency's major product areas—foods, human drugs, biologics, animal drugs and feeds, and medical devices and radiological products. Five Regional offices (Northeast, Central, Southeast, Southwest, and Pacific) are under the control of RFDDs, who report directly to the ACO. Each Regional office supervises two to seven District offices, each led by a Director. There are currently 20 District offices located in major cities around the country.

Figure C-3 illustrates the FDA Regional and District offices across the Nation.

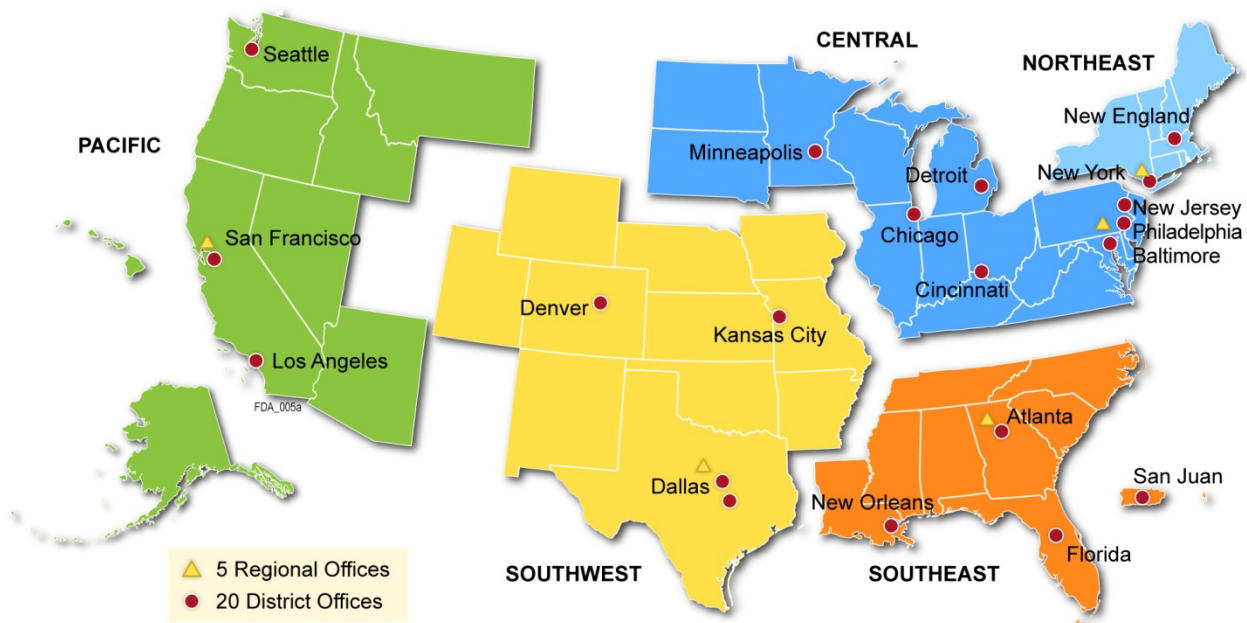


Figure C-3. FDA Regions and Districts

In addition to conducting normal surveillance over regulated products, FDA Regional and District offices serve a critical emergency response function by immediately mobilizing to investigate reports of product problems. These field organizations work to verify product information and secure any suspect products. They obtain additional information by reviewing records and examining products to focus follow-up actions and may collect samples for laboratory analysis. The field staff also work with other Federal and SLTT agencies to detain, seize, and/or embargo products in support of public health; request State officials to hold suspect products; issue requests to industry for voluntary holds or suspension of operations; request and monitor industry recalls; conduct necessary inspections; conduct traceback²⁹ investigation work; and monitor the effective disposition of adulterated/misbranded product.

C.5.2.4.5.1 Forensic Chemistry Center

The Forensic Chemistry Center (FCC), located in FDA's Central Region, reports directly to the Regional Director. Its personnel perform laboratory research and analyses on a day-to-day basis, regularly providing expert technical support for FDA's OCI as its primary laboratory. The laboratory also provides forensic analyses of samples for the rest of ORA, OC, CFSAN, CDER, CVM, CDRH, and other Federal and State agencies. The FCC plays a major role in many programs initiated by FDA, particularly anti-counterfeiting, anti-tampering, and counterterrorism.

C.5.2.4.5.2 Winchester Engineering and Analytical Center

The Winchester Engineering and Analytical Center (WEAC), located in FDA's Northeast Region, reports directly to the Regional Director. WEAC holds FDA's U.S. Nuclear Regulatory Commission (NRC) Materials License, and its personnel perform radionuclide-related laboratory research and analyses on a day-to-day basis. WEAC serves as FDA's sole radiation analytical laboratory and provides radio-analytical analyses for samples, as well as lead responsibilities for the radiation safety program for ORA field offices.

²⁹ For more information on how the FDA conducts traceback investigations, refer to the FDA EOP Appendix H, *Domestic and International Traceback/Traceforward*.

D. DIRECTION, CONTROL, AND COORDINATION

FDA organizes emergency response operations in accordance with the concepts, principles, and terminology of the ICS, as defined within NIMS.³⁰ Incident Command and subordinate Planning, Operations, Logistics, and Finance/Administration functions lay the foundation for the agency's implementation of the ICS during all-hazards response, at headquarters and field levels, and across geographic divides. The inherent design of this system enables rapid, scalable, and flexible agency-wide emergency management activities. **Figure D-1** and **Figure D-2** depict FDA's emergency response coordinating structure and are followed by a brief description of each designated ICS position.³¹

This section of the FDA EOP describes FDA's application of the ICS. It is important to remember that two key principles of ICS are its scalability and flexibility. Emergency and disaster situations can be unpredictable and dynamic. To accommodate this, the ICS organizational structure was developed to be expanded easily from a very small size for routine operations to a larger organization capable of handling catastrophic events. Therefore, FDA's organizational structure, while containing certain core positions, must be tailored to the specific requirements of each incident. Refer to the FDA EOP Incident Annexes for detailed information on FDA organizational constructs for individual hazards.

For individual Center/Office emergency response organizations within this basic structure, refer to each organizational component's EOP and/or SOPs.

D.1 FIELD INCIDENT COMMAND

The use of Incident Command in the field is achieved through the establishment of an IMT at appropriate field location(s) to identify field incident response objectives and execute the tactical implementation of headquarters' strategic plan for responding to an incident. IMTs can follow a Regional or District strategic plan in addition to or in the absence of a headquarters plan. An IMG and IMT may or may not mobilize and/or demobilize concurrently.

The field IC(s) will direct the field personnel to conduct tactical operations to determine the cause/source of the emergency and/or resolve the emergency in accordance with the IAP they develop and, in some cases, based on information, analysis, and direction received from the IMG. Depending on the nature and stage of the emergency, these operations might include, among other things, facility or field inspections, sample collection, laboratory analysis, traceback and traceforward investigations, import-related activities, recall efforts, and enforcement actions. In conducting these operations, Incident Command might interact with regulated entities, FDA headquarters, State and local officials, other Federal Agencies, foreign regulatory authorities, and regional/local news media.³²

When appropriate, the FDA field IC may be part of a UC with multiple ICs representing different agencies (e.g., FDA and a State health agency) or jurisdictions (e.g., Federal, State, local). The field IC may also be requested to provide a Liaison Officer (LNO) to a Regional or local UC.

³⁰ For more information on the ICS, refer to www.training.fema.gov/EMIWeb/IS/ICSResource/index.htm.

³¹ Depending on the level and complexity of incident requirements, certain agency ICS functions and positions may not be necessary. Refer to the FDA EOP Incident Annexes for specific personnel assignments.

³² The IMG Public Information Officer coordinates development and release of agency public health and consumer protection messages for use with the public, media, and/or other agencies with approval from FDA headquarters and HHS.

An IMT functions in accordance with ICS principles and is headed by an IC, who may establish Operations, Planning, Logistics, and/or Finance/Administration Sections, as needed, to manage the agency's on-the-ground response (**Figure D-1**).

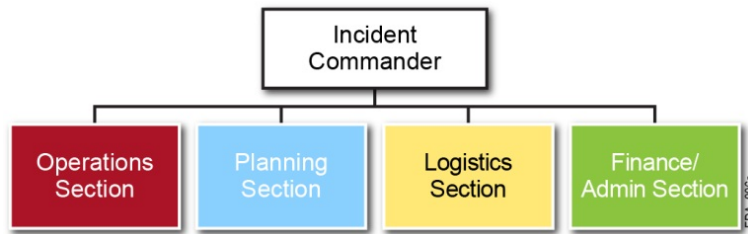


Figure D-1. FDA Field Incident Management Team

When multiple District IMTs are involved in responding to the same incident, an Area Command Structure may be established to oversee management of the incident. When multiple agencies are responding at the field level to the same incidents, a UC may be used in the field to establish a common set of objectives and strategies and a single IAP. If multiple agencies and jurisdictions are responding at the field level to the same incident, a Unified Area Command can be used in the field to provide command authority and coordination.

D.2 HEADQUARTERS INCIDENT COORDINATION

When necessary, headquarters will activate an incident coordination structure referred to as the IMG. (See *Section B.2.2.3.3*, “FDA Headquarters Response – IMG” regarding which FDA officials have the authority to activate an IMG.) The IMG facilitates the integration of all FDA assets responding to an incident as required by the NRF. As the agency’s coordination structure, the IMG serves as the focal point for headquarters-level strategic coordination and provides recommendations for actions to take and priorities for the use of resources in support of incident management. The IMG has general oversight of the application of FDA resources in coordination with existing agency and interagency resource management. It provides strategic situational awareness and decision support across the full spectrum of incident management domains—prevention, protection, mitigation, response, and recovery.

Because of FDA’s unique organizational structure, which involves emergency response resource and capabilities from multiple Centers and Offices, the FDA IMG coordinates unified agency responses to incidents, which is somewhat similar to an Area Command. The goal of the IMG is to facilitate a comprehensive, integrated, and coordinated approach to domestic and international incident management.

For its coordination structure, FDA may adapt the headquarters-based Incident Command structure to address the scope of the incident, which at times acts as a hybrid coordination and command structure, as in the case of a pandemic influenza response. **Figure D-2** is an example of how an IMG may be organized. This structure is flexible, and parts of it may be expanded or contracted as the emergency evolves.

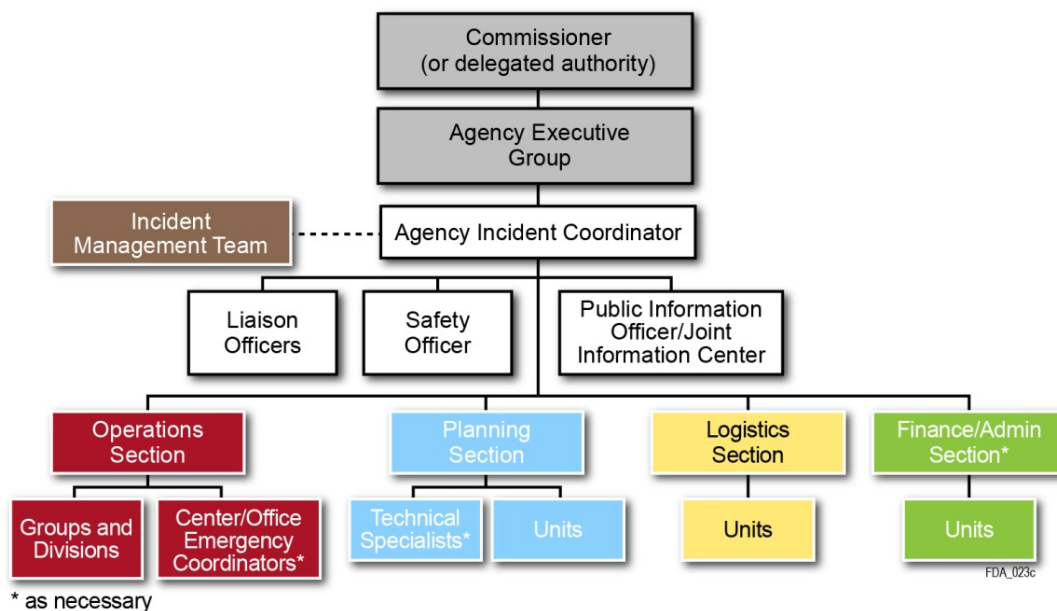


Figure D-2. FDA Headquarters Incident Management Group

The FDA EOC may request the FDA product Centers and OC Offices provide staff to support emergency operations based on the subject matter expertise required. FDA product Centers and OC Office staff may hold any position in the IMG (Command or General Staff) as requested by the AIC.

D.2.1 Command Staff

D.2.1.1 Agency Incident Coordinator

The AIC has overall delegated authority and responsibility for agency-wide emergency operations and ensures information review for appropriate action, including referral to the Commissioner or AEG for executive-level direction or to headquarters or field units for any necessary follow-up. In addition, the AIC serves as the central point for headquarters coordination regarding issues and decisions involving FDA organizational components, the HHS SOC, other HHS OPDIVs and Staff Divisions, applicable Federal and State agencies, and foreign governments. The AIC is responsible for assigning the Operations, Planning, and other Section chiefs or, when these additional positions are not required, personally accomplishing or managing these aspects of the incident organization.³³ If an IMG is activated, the AIC and designated support staff will be physically located in the EOC, unless weather, building emergencies, or some other unforeseen circumstance prevents it.

Until the Commissioner, Deputy Commissioner, or other designated senior agency official appoints an AIC for any emergency or disaster involving multiple FDA organizational components and/or requiring external coordination, the OCM/OEO Director will serve as the AIC and will report to the Commissioner or his/her authorized designee. He/she is responsible for coordinating and providing situational awareness on all incident activities performed at the headquarters and field levels.

The AIC responsibilities are to:

- Develop broad objectives for agency-wide emergency response operations.
- Coordinate with engaged headquarters and field Centers/Offices in the development of individual incident objectives and strategies.
- Allocate/reallocate agency resources as the established priorities change.
- Ensure effective communications between headquarters and field organizational components.
- Ensure overarching incident management objectives are met and do not conflict with each other or with agency policies.
- Identify and report on critical agency resource needs.
- Facilitate FDA's transition to full recovery operations.
- Establish communications channels with any field Incident Command structure (e.g., IMT).

The FDA Command Staff of the IMG and possibly in the field includes a Public Information Officer (PIO) and LNOs who report directly to the AIC. Additional Command Staff positions may be required, depending on the nature, scope, complexity, and number of locations of the incident(s), or according to specific requirements established by the AIC. At headquarters, a Legal Advisor may be assigned to the Command Staff as a Technical Specialist or to the Planning Section to advise the AIC on legal matters, such as emergency proclamations, and the legality of EUAs (legal rights and restrictions pertaining to product use). Similarly, a Medical Advisor or Science Advisor may be designated and assigned directly to the Command Staff to provide advice and recommendations to the AIC in the context of incidents involving medical and public health response or medical countermeasures considerations. Command Staff positions are discussed in the paragraphs that follow.³⁴

³³ Refer to the *FDA Incident Management Handbook* for the specific time-phased emergency actions of the AIC.

³⁴ Refer to the *FDA Incident Management Handbook* for specific time-phased emergency actions of the Command Staff.

D.2.1.2 Liaison Officers

LNOs interface or report from external Federal Agencies (i.e., HHS, CDC, USDA, EPA, DHS, FBI, or DOS) as representation to FDA during an incident. These Command Staff members serve as direct links between the AIC and their agency, providing input on their agencies' policies, activities, concerns, resource availability, and other incident-related matters. These LNOs are responsible for maintaining an awareness of the situation, reporting relevant information, and facilitating communication regarding FDA requests for assistance from the LNO's agency. Staff assigned to these positions must have the authority to speak for their parent agencies or organizations on all matters, following appropriate consultations with their agency leadership. Assistants and personnel from other agencies or organizations, public or private, involved in incident management activities may be assigned to the LNO to facilitate coordination. There may also be a need for a liaison with industry.

D.2.1.3 Safety Officer

The Safety Officer monitors incident operations and advises the AIC on all matters relating to operational safety, including the health and safety of emergency responder personnel. The Safety Officer is, in turn, responsible to the AIC for the systems and procedures necessary to ensure ongoing assessment of hazardous environments, including the incident safety plan, coordination of multiagency safety efforts, and implementation of measures to promote emergency responder safety as well as the general safety of incident operations. The Safety Officer has immediate authority to stop and/or prevent unsafe acts during incident operations. It is important to note that the agencies, organizations, or jurisdictions that contribute to joint safety management efforts do not lose their individual identities or responsibility for their own programs, policies, and personnel. Rather, each contributes to the overall effort to protect all responder personnel involved in incident operations.

D.2.1.4 Public Information Officer

The FDA JIC will be led by the IMG PIO and Deputy IMG PIO. The IMG PIO works with the appropriate FDA organizational components such as the product Centers and OEA to coordinate message development and dissemination.³⁵ FDA has specific policies for handling public information. The IMG PIO major responsibilities generally apply to any type of incident involving an FDA-regulated product. Additional staff may be tasked to support the IMG PIO.

The FDA IMG PIO maintains regular communications with OEA as well as other Center and Office (i.e., OIP) public affairs and communications staffs and informs the IMG of any associated public information activities, concerns, and information requests. The IMG PIO is not necessarily the incident spokesperson, but the coordinator of message development and dissemination.

In addition to the headquarters role, there may be one or more field IMT PIOs. The IMT PIO maintains an accurate account of information about the incident to inform and update the IMG PIO. For FDA incidents, the on-scene PIO must coordinate all information and media interactions with the IMG PIO.

The relationship between these entities is illustrated in **Figure D-3**. Proper media clearance channels through HHS are not superseded by the figure below.

³⁵ For more information, refer to the *FDA Joint Information Center Handbook*.

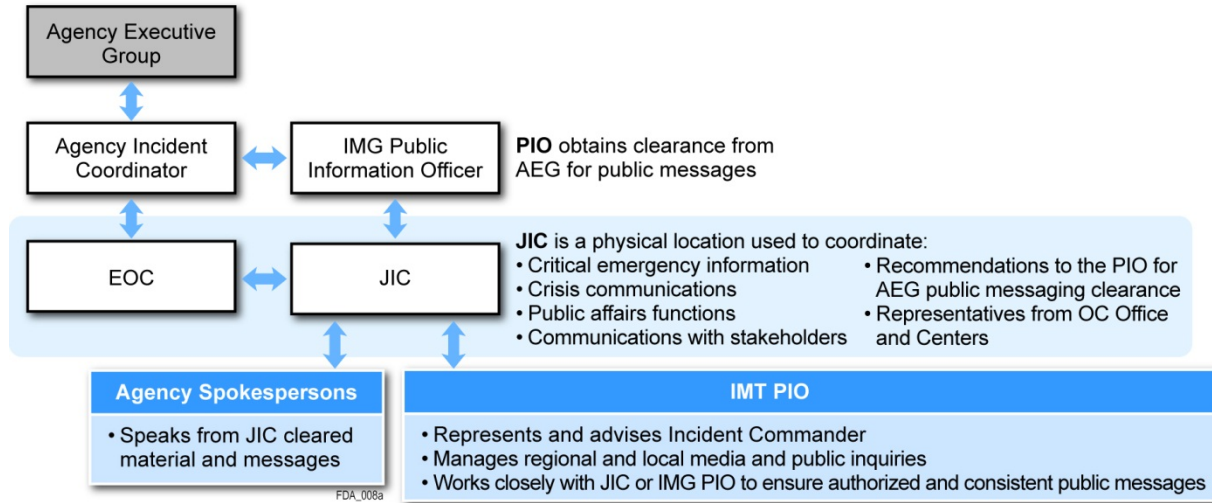


Figure D-3. FDA's Joint Information System

The FDA JIC staffing composition and structure are determined by the various methods FDA uses to reach its multiple audiences. The following structure (**Figure D-4**) depicts the groups and liaisons that could be part of a FDA JIC.

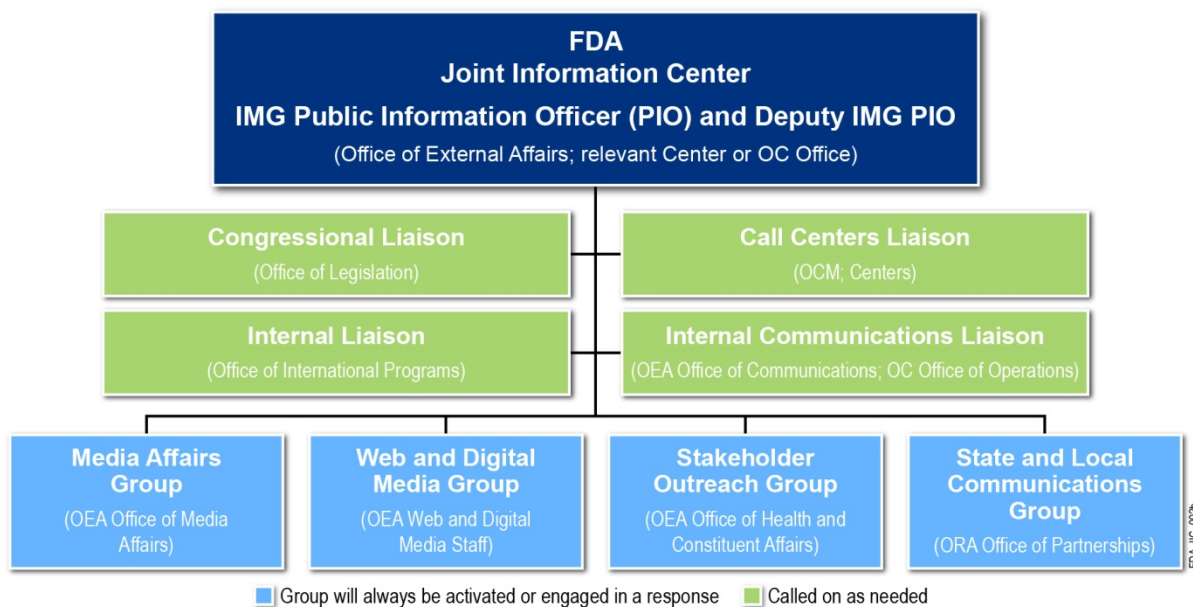


Figure D-4. FDA Joint Information Center Possible Structure

The majority of incidents to which FDA responds do not call for all eight reporting elements depicted in the FDA JIC figure above. The four groups are the elements most likely to be activated. When span of control becomes an issue for the IMG PIO, the IMG Deputy PIO may be assigned to manage the FDA JIC staff.

D.2.1.4.1 FDA Joint Information Center

Dependent on the incident's strategic communication objectives, the IMG PIO's responsibilities may be shared among other individuals and Offices in a FDA JIC as part of a larger Joint Information System (JIS).³⁶ FDA's JIC is a physical collocated group of representatives from the FDA Offices and Centers involved in the event who are designated to handle public information needs. The FDA JIC monitors and assesses the need for and effectiveness of public messaging regarding the incident and FDA's response. The FDA IMG PIO works with the FDA JIC to provide a public messaging strategy for the incident. The AIC and AEG³⁷ approve the strategy and messages. Target audiences include consumers, industry, Congress, and health professionals.

The FDA JIC will be established in proximity to FDA's EOC to provide a base of operation for the public information function to facilitate timely communication among its members. If a physical location within FDA facilities is not possible, the FDA JIC may function as a group using electronic communications such as conference calls, e-mails, and instant messaging. The FDA JIC will be activated when the IMG PIO and the AIC deem it will benefit the incident objectives to have the communication strategies coordinated in the same physical location or by electronic communications.

An interagency unified JIC may be established at the national level to ensure consistent and accurate public messages are issued when multiple agencies and organizations are involved in a response. An interagency JIC is a collocated or collaborating group of representatives designated by their agencies and organizations to participate in the joint development, coordination, and delivery of public messages. An interagency JIC ensures the coordinated release of information under two NRF annexes—ESF #15 – External Affairs Annex and the Public Affairs Support Annex. If FDA is asked to participate in an interagency JIC, the IMG PIO will identify someone to serve as FDA's representative on the interagency JIC. This representative will serve as a liaison to FDA's JIC and report to the IMG PIO.

D.2.1.4.2 Media Relations Group

During an incident response, the Associate Commissioner for External Affairs, in conjunction with the Director of OEA's OMA, will appoint an experienced staff media officer to lead the FDA JIC's Media Relations Group with responsibility for managing the news media outreach activities and message development of the FDA JIC.

D.2.1.4.3 Web and Digital Media Group

During an incident response, the Associate Commissioner for External Affairs, in consultation with the Director of OEA's Web and Digital Media staff, will appoint a lead for the FDA JIC Web Group to manage the agency's Web and digital communications related to the incident, including Web postings (e.g., portals, response questions and answers [Q&As]), FDA Voice blog, Twitter, Facebook, Flickr, widgets, searchable databases (for extensive recalls), postings on www.foodsafety.gov, or other Government-wide websites such as www.recalls.gov.

³⁶ **Joint Information System:** Integrates incident information and public affairs into a cohesive organization designed to provide consistent, coordinated, accurate, accessible, timely, and complete information during crisis or incident operations. The mission of the JIS is to provide a structure and system for developing and delivering coordinated interagency messages; developing, recommending, and executing public information plans and strategies on behalf of the IC; advising the IC concerning public affairs issues that could affect a response effort; and controlling rumors and inaccurate information that could undermine public confidence in the emergency response effort.

³⁷ **Agency Executive Group:** The AEG is established when an emergency calls for the involvement of senior FDA officials with the knowledge and authority to address a wide range of issues that may arise. The AEG, whether convened as a collective unit or acting as individual members, serves primarily to provide strategic policy direction and guidance for major agency emergency response activities and to approve important policy decisions in consultation with the Commissioner and AIC when necessary.

D.2.1.4.4 Stakeholder Outreach Group

During an incident response, the Associate Commissioner for External Affairs, in conjunction with the Director of OEA's Office of Health and Constituent Affairs (OHCA), will appoint a lead for the Stakeholder Outreach Group to manage outreach to and message development for external stakeholders, as part of the FDA JIC. As needed, representatives from other OC Offices or Centers will be added to the group. For example, OEA's Office of Communications will frequently be involved in advising on consumer messages and preparing external communications materials such as Consumer Updates, FDA Voice blogs, and FDA Fact Sheets.

For FDA, the term stakeholder includes industry and industry associations, consumers and patients, health professionals, scientists and researchers, and the general public, among others.

D.2.1.4.5 State and Local Officials Group

During an incident response, the Director of ORA's OP, in consultation with the Associate Commissioner for External Affairs, will appoint a lead for the State and Local Officials Group to manage the outreach and two-way communications with State and local officials as part of the FDA JIC.

D.2.1.4.6 Call Centers Liaison

During an incident response, the Associate Commissioner for External Affairs, in consultation with Directors of OCM and Center/Office communications offices, will appoint a Call Centers Liaison to the FDA JIC to ensure that up-to-date messages related to the incident and response are available to the general public and industry through the relevant agency Call Centers (if needed).

D.2.1.4.7 Congressional Liaison

During an incident response, the Associate Commissioner for Legislation, in conjunction with the Associate Commissioner for External Affairs, will appoint a Congressional Liaison to manage communications with congressional members as part of the responsibilities of the FDA JIC (if needed).

D.2.1.4.8 International Liaison to External Unified JIC

If an incident includes an international dimension, the Associate Commissioner for International Programs, in conjunction with the Associate Commissioner for External Affairs, will appoint an International Liaison who will manage communications with international partners as part of the FDA JIC (if needed).

D.2.1.4.9 Internal Communications Liaison

During an incident response, the Associate Commissioner for External Affairs, in consultation with OEA's Assistant Commissioner for Communications and the Associate Commissioner for Operations, will appoint an Internal Communications Liaison to ensure that FDA employees receive up-to-date information about the incident and the agency's response efforts (if needed).

D.2.2 General Staff

The General Staff is responsible for the functional aspects of any ICS. The General Staff consists of Operations, Planning, Logistics, and Finance/Administration Sections composed of designated FDA headquarters and field emergency staff. The responsibilities associated with these Sections are discussed more fully below.³⁸

D.2.2.1 Operations Section

The Operations Section is responsible for coordinating all agency activities in response to an identified threat or hazard, establishing an agency-wide common operating picture, and restoring normal operations. This Section may be composed of a Section Chief, Divisions, and Groups (each led by a designated Supervisor). **Figure D-5** depicts FDA's Operations Section.

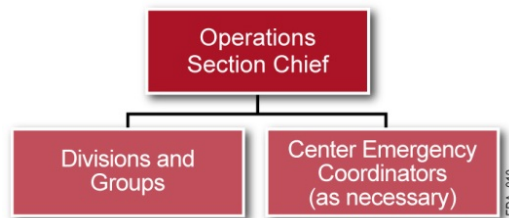


Figure D-5. Operations Section Organizational Elements

Expansion or contraction of the Operations Section may vary according to numerous considerations and operational factors associated with an incident. In some cases, a functional approach may be used. In other cases, the organizational structure will be determined by geographical or Center/Office jurisdictional boundaries or a mix of functional and geographical considerations may be appropriate. The AIC will determine the appropriate organizational structure, based on previous experience and the specific circumstances of the incident at-hand.

D.2.2.1.1 Operations Section Chief

Until the AIC appoints an Operations Section Chief, an emergency coordinator from OCM/OEO designated by the AIC will fulfill the role. The Operations Section Chief is responsible to the AIC for managing incident activities required to implement the agency ICP, as well as providing the AIC with regular status reports. The Operations Section Chief monitors initial and ongoing headquarters and field response activities, advises and assists the AIC on appropriate courses of action, responds to requests for assistance from internal organizational components and external partners, and coordinates regular status/situation updates throughout the lifecycle of the incident. He/she has direct involvement in providing input to and implementing the ICP and serves as the focal point for intra- and interagency coordination and communications. The Operations Section Chief is collocated with the AIC at the FDA EOC.

D.2.2.1.2 Divisions and Groups

Divisions may be established within the Operations Section to assign responsibility based on the physical/geographic location(s) of an emergency or major disaster. Groups may also be assembled to combine similar activities being addressed for a single or multiple incident(s). For example, geographic Divisions may be created in support of a single or multiple responding FDA Regions/Districts, or to coordinate operations when a foreign country is involved. Functional Groups, on the other hand, may include personnel addressing investigations, enforcement, traceback, laboratory analysis, and other issues, depending on the nature and scope of the incident. Divisions and Groups are staffed by representatives

³⁸ Refer to the *FDA Incident Management Handbook* for specific time-phased emergency actions of the General Staff.

from the OC, ORA, and Centers and may change both in designation and composition based on the specific incident requirements. They typically operate from the FDA EOC or alternate workspace locations as needed. A Supervisor shall be designated for each to oversee operations and provide status/situation reporting to the Operations Section Chief.³⁹

D.2.2.1.3 Center/Office Emergency Coordinators

FDA product Centers and OC Offices shall designate a senior staff member and alternates to serve as the Center/Office Emergency Coordinator. The Center/Office Emergency Coordinator is responsible for advising the Center/Office Director of actions needed to address an incident, supervising and reporting on the Center's/Office's emergency response activities, and channeling necessary communications between the Center and other FDA organizational components (e.g., other Centers/Offices and the FDA EOC). He/she serves as the focal point for internal and external Center/Office communications during emergencies and disasters and is responsible for providing regular status reports as requested. During some large-scale or catastrophic incidents, Center/Office emergency coordinators may be directed to report to the FDA EOC to support initial or prolonged emergency operations.

D.2.2.2 Planning Section

The Planning Section is responsible for collecting, evaluating, and disseminating information pertaining to the incident. This Section documents and maintains information on the current and forecasted situation, as well as the status of FDA resources assigned to the incident. The Planning Section prepares the IMG ICP, compiles and consolidates FDA-wide SitReps, and organizes status/situation reporting meetings and teleconferences. As shown in **Figure D-6**, the Planning Section, led by a Section Chief, may include subordinate units (i.e., Resources, Situation, Documentation, and/or Demobilization) and Technical Specialists from FDA headquarters Centers and Offices to assist in evaluating the situation and forecasting requirements for additional agency resource support.

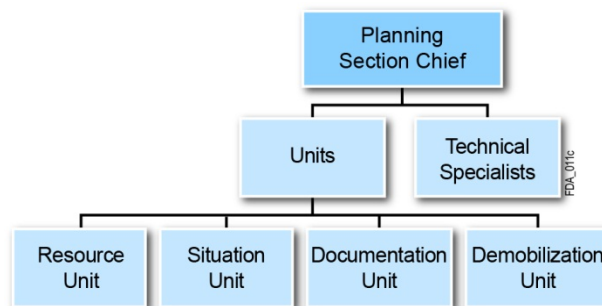


Figure D-6. Planning Section Organizational Elements

D.2.2.2.1 Planning Section Chief

Until the AIC appoints a Planning Section Chief, an emergency coordinator from OCM/OEO designated by the AIC will fulfill the role. This individual oversees all data gathering and analysis activities regarding incident operations and assigned resources, coordinates planning and status/situation reporting meetings, and prepares the ICP. The Planning Section Chief is collocated with the AIC and Operations Section Chief at the FDA EOC. The Planning Section Chief is responsible for supervising the preparation and distribution of SitReps. See *Section E.1.2, "Situation Reporting"* for additional information on SitReps.

³⁹ Refer to the Incident Annexes of this EOP for detailed information on the functional groups established within the Operations Section to address specific incident requirements.

D.2.2.2.2 Units

The Planning Section may have up to four primary units (described below) that support the Section Chief.⁴⁰ Generally composed of headquarters staff, each unit operates from the FDA EOC unless otherwise directed.

- **Resource Unit.** Makes certain that FDA resources (i.e., personnel, teams, and equipment) are available for assignment to or deployment during an incident. During IMG activations, the Planning Section Chief will generally activate a Status/Check-In Recorder under the Resource Unit, who will maintain an accurate record of all personnel reporting to and demobilizing from the IMG.
- **Situation Unit.** Collects, processes, analyzes, and organizes ongoing situation information; prepares situation summaries; and develops projections and forecasts of future events related to the incident.
- **Documentation Unit.** Maintains a record of the major steps taken to resolve the incident and files incident records for legal, analytical, and historical purposes.
- **Demobilization Unit.** Develops an Incident Demobilization Plan that includes specific instructions for agency resources to return to normal operations.

D.2.2.2.3 Technical Specialists

Technical Specialists have specialized skills and are activated only when needed.⁴¹ Technical Specialists are most often assigned to the specific area (e.g., Section, Branch, Unit, Division) where their services are needed and performed. These headquarters personnel may be assigned to the Planning Section, but may support any ICS function, including the Command Staff working directly for the AIC. Technical Specialists normally perform the same duties during an incident that they perform in their everyday jobs and operate from normal locations unless directed to report to the FDA EOC by the Planning Section Chief or AIC.

The following are examples of the kinds of specialized expertise that may be required during an emergency or disaster:

- **Geographic Information Specialist.** Collects, analyses, and disseminates location-based information to support the objectives of the IMG. Common roles include identifying areas affected by the incident and locating FDA assets and regulated industry. The Geographic Information Specialist produces maps and data products for use in situational awareness, operations management, and reporting. Requests for maps should be submitted to the Geographic Information Specialist. The Geographic Information Specialist position is normally located under the Planning Section but may assist other Sections of the headquarters IMG and field IMT as necessary.
- **Legal Specialist.** Provides advice on issues that involve application or interpretation of relevant statutes and regulations. For example, in some situations involving possibly adulterated food, the Legal Specialist might advise the IMG on the legal aspects of requesting records from food facilities under Section 414 of the FD&C Act. The Legal Specialist also reviews any EUA requests that might be submitted to the agency regarding medical countermeasures needed to protect responders and the public. In addition, the Legal Specialist considers legal issues in media releases and other documents prepared for the incident response. The Legal Specialist usually is a Manager or other Senior Attorney in the OCC.

⁴⁰ The incident itself will primarily dictate the need for Planning Section units. Refer to the Incident Annexes of this EOP for detailed information on the types and composition of units needed for each situation.

⁴¹ The incident itself will primarily dictate the need for Technical Specialists. Refer to the FDA EOP Incident Annexes for detailed information on the types and numbers of Technical Specialists needed for each situation.

- **Science/Medical Specialist.** Advises on scientific and/or medical issues that arise during the response. The Science/Medical Specialist will have expertise in the scientific and/or medical aspects of the incident and will typically be a staff member from the lead Center(s) for the emergency.
- **International Specialist.** As a staff member from OIP, advises on international issues that arise during the response.
- **EUA/Product Interface Specialist.** Typically a staff member from OCET who advises on emergency use and other medical countermeasure issues that arise during the response. The EUA/Product Interface Specialist also leads the coordination of cross-agency activities related to medical countermeasure use and availability activities.

As needed, other Technical Specialists with expert knowledge in the following areas may be required:

- | | | |
|-----------------------------|----------------|-----------------|
| • Human/veterinary medicine | • Pharmacology | • Statistics |
| • Biology | • Epidemiology | • Engineering |
| • Chemistry | • Toxicology | • Data analysis |

D.2.2.3 Logistics Section

The Logistics Section is responsible for all service support requirements needed to facilitate effective and efficient agency incident management operations. This Section provides facilities, transportation, security, supplies, communications, and IT support services to FDA headquarters and field personnel as required. The Logistics Section is led by a Section Chief. This role is initially filled by an OCM staff member; unless designated otherwise by AIC, support units may be staffed from the Office of Management (OM), OIM, and other headquarters Offices as appropriate.

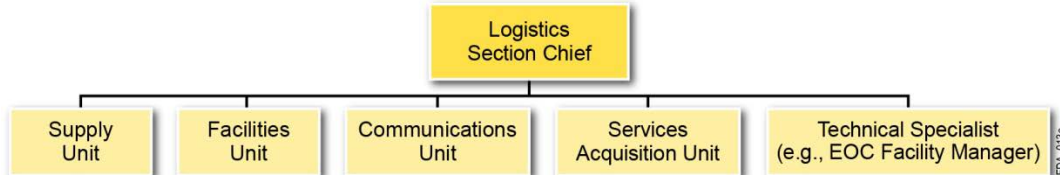


Figure D-7. Logistics Section Organizational Elements

D.2.2.3.1 Units

Units, such as Supply, Facilities, Communications, and Services Acquisition (described below), may be established within the Logistics Section based on the scope and complexity of incident operations. Composed of headquarters staff, each unit operates from normal work locations unless otherwise directed. The Logistics Section Chief will determine, in coordination with the AIC and given current and anticipated requirements, the need for establishing specific subordinate units.

- **Supply Unit.** Coordinates ordering, receiving, processing, storage, inventory management, and distribution of supplies and materials for headquarters personnel.
- **Facilities Unit.** Coordinates headquarters facility operations and building security support services during incident operations.
- **Communications Unit.** Coordinates headquarters IT systems and equipment in support of incident operations and supervises and operates the Communications Center.
- **Services Acquisition Unit.** Coordinates requirements for contracted services needed during the emergency response.

D.2.2.3.2 Technical Specialists

Technical Specialists have specialized skills and are activated only when needed. These headquarters personnel are assigned to the Logistic Section, but may support any ICS function. Technical Specialists normally perform the same duties during an incident that they perform in their everyday jobs and operate from normal locations unless directed to report to the FDA EOC by the Logistics Section Chief or AIC. The OCM EOC Manager is an example of a Technical Specialist who may be required during an emergency to provide specialized expertise.

D.2.2.3.3 EOC Facility Manager

The EOC Facility Manager can be called up to assist the IMG in performing the emergency response operations, which requires that EOC communication capabilities be functioning at all times, including access to network, databases, and the Internet. The EOC Facility Manager is responsible for the technical requirements during COOP relocations and the operation of the EOC.

In addition, the EOC Facility Manager may assist with the transmission of electronic information during an emergency and analysis of information/data needs for a response. Onsite, the EOC Facility Manager coordinates all enhancements of the agency's data information systems, which pertain to critical and time-sensitive information.

D.2.2.4 Finance/Administration Section

A Finance/Administration Section⁴² is established only for those incidents requiring large-scale or extended agency operations or specific financial and administrative support services. Some of the functions that fall within the scope of this Section are accounting, payment processing, financial reporting, foreign and domestic travel expenditures, employee relocation, payroll liaison, and financial systems management. The Finance/Administration Section is led by a Section Chief designated by ORA and staffed with support personnel from ORA, OFM, and other Centers/Offices as appropriate.

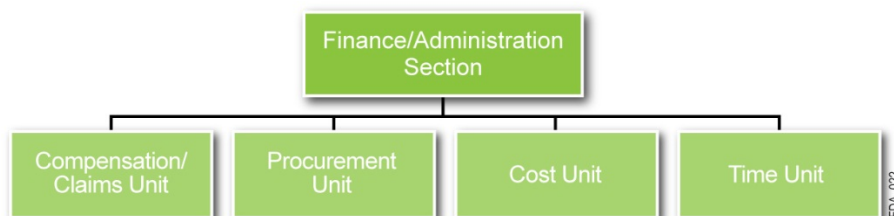


Figure D-8. Finance/Administration Section Organizational Elements

D.2.2.4.1 Units

Units, such as Compensation and Claims, Procurement, Cost, and Time (described below), may be established within the Finance/Administration Section based on the scope and complexity of incident operations. Composed of headquarters staff, each unit operates from normal work locations unless otherwise directed. The Finance/Administration Section Chief will determine, given current and anticipated requirements, the need for establishing specific subordinate units.

- **Compensation and Claims Unit.** Handles agency injury/illness compensation and claims.
- **Procurement Unit.** Administers all financial matters pertaining to vendor contracts and is modified as needed.

⁴² In certain incidents, the Logistics and Finance/Administration Sections may be collapsed together under one Branch. During an influenza pandemic or alert, it is likely FDA's ICS organizational structure will expand to include Logistics and Finance/Administrative as part of the response.

- **Cost Unit.** Provides cost analysis data for the incident.
- **Time Unit.** Ensures proper daily recording of personnel time in accordance with FDA policies.

D.2.3 Agency Executive Group

The AEG is established when an emergency requires the involvement of senior FDA officials with the knowledge and authority to address a wide range of policy and resource issues. The AEG serves primarily to provide strategic policy direction and guidance for major agency emergency response activities and to approve important policy decisions, in consultation with the Commissioner and AIC. Decisions that may be within the AEG's scope include addressing unprecedented legal, regulatory, policy, and resource problems and impasses brought about by the emergency and that impact the agency's ability to respond effectively.

Typically, members of the AEG include:

- Counselor to the Commissioner or designee
- OCM Director or Designee
- ORA Associate Commissioner or Deputy Associate Commissioner
- RFDD(s)
- OEA Associate Commissioner
- Senior leadership from appropriate Offices/Centers (i.e., OCS/OCET, OCC, OGROP/OIP, OFVM, OPP, and OO/OFBA/OB) or their representatives

D.2.4 Multiagency Coordination

Many of the incidents to which FDA responds involve other agencies that have a stake in providing response or needed resources. If the product involved in an incident crosses agency jurisdictional lines, the Multiagency Coordination (MAC) system may be used to support a unified coordination of operations. The primary function of the MAC system is to coordinate activities above the field level and to prioritize incident demands for critical or competing resources, thereby assisting the coordination of field operations.

In this unified coordination approach, representatives from each agency meet to set goals and decide how each agency can contribute to the achievement of the goals. There can be strong, formal command and control relationships between and among the agencies, or the command and control linkages can be based on informal but structured arrangements that recognize Federal and State responsibilities. It can be as simple as a teleconference or, alternately, require an assembled group and associated support systems. Such an assembled group comprises senior officials from the agencies involved in the response who are brought together to form a MAC Group, providing executive guidance to individual agency Incident Command groups on policy, resource allocation, and communications.

A MAC Group may be supported by a MAC Group Coordinator, who may supervise MAC Group Situation Assessment and Resources Information Units that collect and assemble information needed for the MAC Group to fulfill its mission. These units would obtain such information from the agency's IMG/IMT. The MAC Group may also have its own Public Information Unit to coordinate summary information and access to information sources with the media and other governmental entities. This function is often called a Joint Information Center (or JIC).

The results of the MAC Group's deliberations are distributed by its members directly to their own organizations as well as through the normal chain of command (e.g., EOCs, Incident Command/Coordination Groups, etc.).

Regardless of the level of Government involved in response to an incident, all MAC Groups have five key functions. These functions include:

1. **Direction and Control.** Provide indirect control and direction for complex or multijurisdictional incidents. Serve as a single POC for prioritizing incidents and for facilitating access to critical resources.
2. **Information Collection and Evaluation.** Serve as a central point for collecting, analyzing, and interpreting information from a variety of sources.
3. **Coordination.** Play a key role in coordinating the information flow and resources for complex incidents or multiple incidents occurring simultaneously.
4. **Priority Setting.** Prioritize incidents and critical resources using the priorities established by the NPG as well as the priorities used to guide development of incident objectives (Life Safety, Incident Stabilization, and Property and Environmental Conservation), and use these priorities at the policy level.
5. **Resource Management.** Manage scarce resources in line with incident priorities; resource management includes identifying and acquiring needed resources in addition to allocating existing or known resources.

D.2.5 Multiagency Coordination Group for Foodborne Illness Outbreaks⁴³

FDA, along with USDA agencies, HHS, and the CDC, has created a Multiagency Coordination Group for Foodborne Illness Outbreaks (MAC-FIO) (see **Figure D-9**). This approach to unified coordination includes a MAC Group that comprises senior officials from each agency, and these personnel provide executive guidance to individual agency Incident Command groups on policy, resource allocation, and communications.

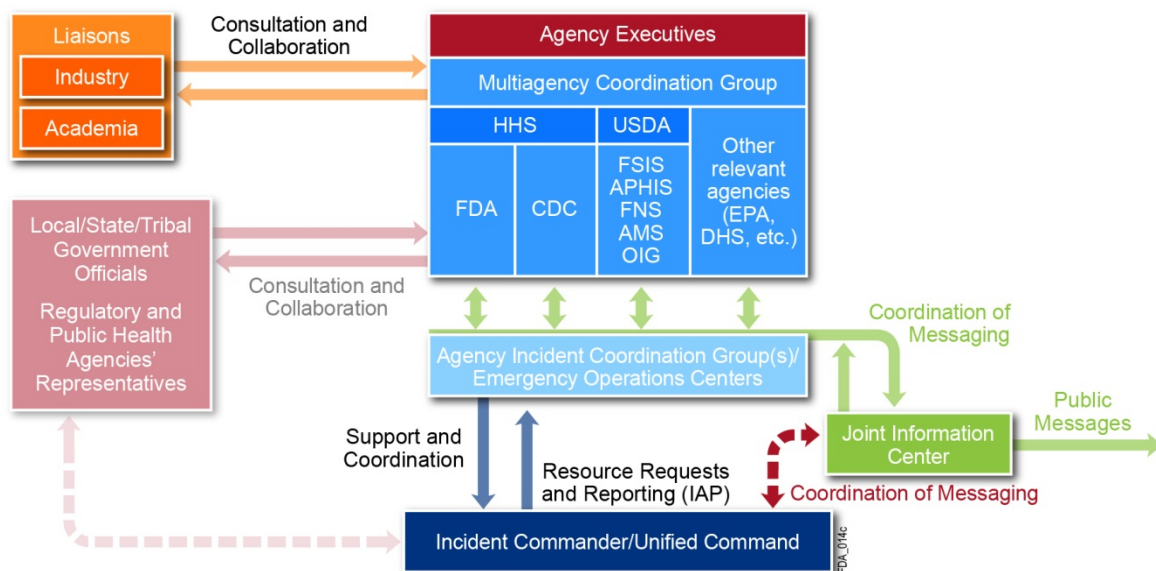


Figure D-9. MAC-FIO Unified Coordination for Foodborne Illness Outbreaks

⁴³ Information excerpted from *FACT SHEET: Multiagency Coordination Group for Foodborne Illness Outbreaks (MAC-FIO)*, November 2012.

The MAC-FIO may be alerted when indicators of a large-scale foodborne illness outbreak potentially involving more than one agency become evident. This pre-alert is intended to ensure the critical coordination among agencies involved under a unified structure for all large-scale foodborne illness outbreaks involving multiple agencies. A formal MAC-FIO in place can also be activated expeditiously to provide the executive guidance to Incident Command through the agencies' response coordinating bodies and ensure:

- Coordination of the development and implementation of a flexible, scalable, and adaptable response among Federal, State, local, and tribal governments to multijurisdictional foodborne illness outbreaks.
- Coordination between law enforcement agencies and public health agencies of investigations of foodborne illness outbreaks due to intentional contamination.
- Coordinated communication strategy to the public, industry, and other international and domestic partners.
- Coordinated collaborative efforts among Federal, State, and local governments in identifying the source of the contamination and removal of contaminated products/ingredients through a coordinated traceback and recall of all contaminated food, feed, and ingredients.
- Coordinated development of measures to prevent future contamination and illnesses.
- Established systematic and proactive approach for managing incidents across multiple jurisdictions as well as established a national-level policy coordination structure.

E. COMMUNICATIONS AND INFORMATION MANAGEMENT

Effective emergency management and incident response activities rely upon flexible communications and information systems that provide for a “common operating picture” across all agency components and staff. Properly planned, established, and used communications processes and systems enable the vertical and horizontal dissemination of information among and between FDA organizational components; with Federal, SLTT, and foreign government agencies; and to the news media, industry, and consumers.

E.1 INTRA-AGENCY COORDINATION

During the course of any incident for which an FDA response may be necessary, timely communications and information sharing among agency units is critical to assist FDA leadership and staff with gaining and maintaining situational awareness and making decisions. Incident information, such as emergency alerts and status/situation reporting, can aid in developing an agency IAP, serve as the basis for releasing public messages, determine the need for involvement of FDA organizational components, and satisfy RFIs. The following are examples of information generated by responsible FDA emergency staff and the technological systems they rely upon for use during an incident to build an agency-wide “common operating picture.”

E.1.1 Emergency Alerts

FDA may be alerted to a threat or hazard through a variety of means, including from FDA headquarters Centers/Offices or Regional/District offices, other government agencies, consumers, and industry. Formal notifications typically occur by phone (primary) to the OCM/OEO with appropriate follow-up by email and/or fax referencing the initial emergency alert.

HHS/FDA/OC/OCM/OEO
10903 New Hampshire Avenue
Building 32, Room 1395
Silver Spring, MD 20993

Main OCM/OEO
301 796 8240

Toll Free Number
1 866 300 4374

Fax Number
EOC: 301 847 8544
Main: 301 847 8543

Email
Emergency.Operations@fda.hhs.gov

An OCM/OEO Emergency Coordinator records the initial call and subsequent follow-up information. After regular duty hours (8:00 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding Federal holidays) and when the Office is not operating, an answering service refers all emergency calls via pager to an OEO Late Duty Officer (LDO). Upon receipt, the Emergency Coordinator or LDO uses a pre-developed call-down tree/notification list for internal and external distribution of emergency alerts.

For each incident, OCM/OEO will provide notification about the incident to those appropriate officials and staff of the Centers and Offices who may have a response role in that particular incident.

Also, the OCM/OEO Director may send notification of EOC operating status level and additional staffing requirements to all involved parties.

E.1.2 Situation Reporting

Standardized incident reporting and documentation procedures ensure that agency-wide situational awareness is maintained and provide emergency personnel with easy access to critical information. Status reports relay information specifically related to the availability or assignment of agency resources. SitReps offer a snapshot of each tasked organizational component's emergency operations and contain confirmed information regarding the explicit details of the incident (who, what, when, where, and how). Transmission of this data in a common format, and at predesignated intervals, enables FDA to rapidly share critical intelligence and information between headquarters and field elements and with external partners as appropriate.

During an incident, FDA IMTs, field offices, and Centers provide regular SitReps via the EON-IMS, which is discussed in-depth below. These SitReps highlight significant event information and emergency response activities (e.g., investigations, analyses, public affairs, cooperating agencies, scientific data, legal court matters). District, Regional, and Center emergency coordinators are responsible for configuring the SitRep process, defining recipients, and reviewing and accepting inputted information.

Once field SitReps have been approved/confirmed by emergency coordinators, the Planning Section Chief, in coordination with Command and General Staff located at the FDA EOC, assembles a consolidated SitRep and posts to the EON-IMS. This report combines relevant data from field SitReps for dissemination across FDA and is used to provide operational information to external Federal Agencies.

E.1.3 Emergency Operations Network – Incident Management System

In addition to primary modes of voice and data communications (telephone and email), the EON-IMS⁴⁴ serves as the central hub for exchanging, storing, and relaying all incident-related information within the agency. Managed by OCM, this system integrates multiple data streams from other electronic systems, such as FERN, the Electronic Laboratory Exchange Network (eLEXNET), Epidemic Information Exchange (Epi-X), and from FDA laboratories and investigators and external agencies, into a coherent fashion during critical decision points. The EON-IMS creates a safety net that significantly reduces the probability that incidents will prevent FDA from accomplishing its objectives and minimizes the impact of these events on normal operations. It provides a Web-based connection for all agency organizational components and their partners through which accurate real-time data about an incident can be shared and discussed, and is used in all situations requiring efficient receipt and dissemination of large volumes of information to FDA stakeholders, including the public and other government agencies.

The EON-IMS, which is critical for comprehensive performance of agency incident management functions, has three components: (1) incident tracking and contact management, (2) a collaboration and knowledge management tool for meetings and document management, and (3) a GIS for mapping and impact assessment. Through EON-IMS, FDA ensures that its emergency response is uniform, consistent, and coordinated. Participants are able to provide input and access real-time data, agency emergency plans and procedures, contact databases, and analysis tools, which enhance response capabilities.

⁴⁴ Additional EON-IMS resources (e.g., user manual, reference sheets, etc.) may be found on the FDA intranet at <http://inside.fda.gov:9003/ProgramsInitiatives/EmergencyPreparednessandResponse/EmergencyOperationsNetworkIncidentManagementSystemEONIMSResources/default.htm> or by contacting OCM.

E.1.4 Government Emergency Telecommunications Service

In response to White House guidance, the National Communications System (NCS) developed the Government Emergency Telecommunications Service (GETS) to ensure key personnel can communicate over local and long-distance telephone networks during an emergency. GETS can provide users a high likelihood of call completion during the most severe conditions of network congestion and disruption. There is an additional feature that can be activated on the GETS card called Wireless Priority Service (WPS). WPS allows GETS users to have their official cell phone number associated with their GETS service and ensures cellular communications are also available.

Located on the back of each GETS card are instructions for its use. For questions concerning GETS cards, call the FDA EOC at 301-796-8242 and ask to speak with the GETS Card Coordinator.

E.2 INTERGOVERNMENTAL COORDINATION

Coordination with responsible government agencies at the Federal and SLTT levels must be effective during emergency and disaster situations to ensure that resource allocations are efficient, policy is understood, and that roles are well defined. Considering that Federal Agency responsibility varies from one type of incident to another, and that State and local government organizations differ from those of the Federal Government, the specific number of agencies that should cooperate in a given situation is highly dependent on the incident at-hand and its location(s) as well. However, specific FDA organizational components are charged with establishing and maintaining communications at the various intergovernmental levels, regardless of incident size, complexity, or geographic location. These headquarters and field organizations are described below.

E.2.1 Communicating with Federal Government Agencies

The FDA EOC staff is responsible for coordinating Federal interagency liaison activities and establishing communications with the headquarters emergency operations offices and staff of Federal Agencies during incidents of varying nature and scope. Through the use of dedicated communications channels, standardized reporting mechanisms, and the deployment of internal and external liaisons, the FDA EOC is able to maintain contact with the HHS SOC, CDC EOC, USDA/FSIS, and other Federal Department/Agency EOCs as appropriate. Centers may have technical consultation with other Government Agencies during an emergency and provide updates about significant consults to the agency through the EOC.

The lead District, in coordination with the FDA EOC, is also responsible for communicating with appropriate Federal field offices and incident management field structures, such as the DHS/FEMA Regional Response Coordination Center (RRCC), JFO, and any established disaster recovery centers.

E.2.2 Communicating with State, Local, Tribal, and Territorial Governments

During an incident, both the lead District and other investigating Districts are responsible for establishing communications with responsible State agencies. Usually, FDA will work through the State in coordinating efforts at the local level or through the use of the State's predesignated RRTs. However, depending upon the State, it may be more appropriate for FDA District offices, in coordination with the FDA EOC, to work directly with local government to address the situation.

The DFSR, within ORA, in cooperation with the appropriate FDA Region(s) and District(s), is responsible for managing FDA's field interaction with SLTT agencies. The DFSR maintains a rapid communication system to alert officials in State governments, major municipalities, and poison control centers and to quickly enlist nationwide assistance for the agency's emergency operations. During an incident, the DFSR will:

- Ensure the appropriate State agencies, such as agriculture and health departments, are notified of significant confirmed incidents within their States or which cross State borders, indicating the potential for problem FDA-regulated products to enter commerce.
- Prepare (or distribute) information requested by States during the course of emergency response operations and ensure they are fully advised as to what action(s) FDA can recommend under the circumstances of the specific incident.

E.2.3 Communicating with Foreign Governments

During an incident when commerce with Canada or Mexico is involved, FDA's response coordination will be performed by the EOC in cooperation with OIP. When commerce with other countries is involved, OIP, in direct coordination with the FDA EOC, will establish, supervise, and/or coordinate and maintain appropriate communication channels.

During emergency response operations, a requirement may exist to conduct secure communications with other government agencies. This situation requires strict adherence to guidelines and regulations for handling, processing, and storing sensitive/classified materials. FDA restricts access to sensitive and classified material to ensure its release to only those agency personnel who possess appropriate security clearances and a need-to-know. OCM/OEO maintains a list of locations and numbers of agency secure voice and data equipment. In direct coordination with OSO, they shall be made available to authorized agency staff on a case-by-case basis.

E.3 PUBLIC MESSAGING

Public messaging consists of the agency processes, procedures, and systems to communicate timely, accurate, and accessible public health and medical information to the media and directly to FDA stakeholders (both directly and indirectly affected). Information must be coordinated and integrated across FDA organizational components at the headquarters and field levels, as well as with other Federal and SLTT government agencies and industry partners to protect consumer well-being and decrease the risk of illness, injury, disease, or death. Well-developed communications plans and strategies executed by responsible FDA staff help to ensure that messages, alerts and warnings, educational materials, and situational updates are developed and distributed to numerous audiences in a timely, consistent manner.

FDA's OMA, within the OEA, is responsible for coordinating the release of information to the public during an emergency or disaster. It serves as the agency's primary liaison with the news media and develops FDA's public health and consumer protection messages. During an emergency, OMA Public Affairs Specialists, in direct coordination with the assigned IMG PIO, Center media representatives, and all responding field offices, issue press releases, media advisories, and other public statements; respond to media requests; and arrange and support media interviews.

OEA's Office of Communications develops and promotes FDA consumer health information, which consists of time-sensitive public health and product safety alerts and information about FDA's roles and responsibilities in protecting and promoting public health. The goals of this Office during an incident include promoting improved outreach and readership of FDA consumer health information, sharing time-sensitive public health and product safety alerts, and facilitating public understanding of FDA's roles and responsibilities in protecting and promoting public health.

OEA's Web and Digital Media staff ensures that vital and important information and consumer health messages are expeditiously posted to FDA's website (www.fda.gov) and updated as needed. The Web and Digital Media staff also coordinates Web communications with OMA, HHS/ASPA, other Federal Agencies, and State and local governments to ensure a consistent and comprehensive approach that reduces duplication of messages.

E.3.1 Coordination with Other Federal Agencies

Coordination with other external Federal Agencies is also conducted to ensure the provision of a common message. In accordance with the NRF, pre-identified incident communications protocols are established and ready for use during an incident requiring a coordinated Federal response.

The National Incident Communications Conference Line (NICCL) is used for transmission and exchange of critical and timely (e.g., "breaking") *incident* information among Federal and affected SLTT authorities. If the nature of the incident is of critical importance and urgency, DHS Public Affairs will maintain a controller on the line continuously to provide and receive updates from departments and agencies. During sustained incident management activity, the NICCL will be used for daily or other incident communications coordination calls. DHS Public Affairs will maintain a summary of key NICCL communications and interagency coordination actions.

Throughout an incident, OMA will take guidance from and work closely with the HHS Office of the Assistant Secretary for Public Affairs (ASPA) in publicizing public health messages and implementing a strategic communications plan that:

- Coordinates and expedites FDA messages with HHS/ASPA and other partners to ensure consistency.
- Disseminates clear and accurate messages that maintain, increase, or restore public trust and confidence.
- Uses a variety of vehicles to distribute public health messages.



OEA also coordinates Web communications with HHS/ASPA, other Federal Agencies, and State and local governments to ensure a consistent and comprehensive approach that reduces duplication of messages.

E.3.2 Congress

FDA's OL directs and manages FDA's legislative needs, pending legislation, oversight activities, and congressional relations consistent with the mission of the agency. In an emergency or disaster, the OL is responsible for, but not limited to, the following activities:

- Keeping Congress apprised of FDA actions relative to the incident in coordination with the HHS Office of the Assistant Secretary for Legislation (ASL).
- Responding to congressional RFIs related to the incident.
- Arranging and supporting congressional meetings, briefings, and hearings.



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F. AUTHORITIES AND REFERENCES

The legal authorities that guide the structure, development, and implementation of the FDA EOP include statutes and regulations, presidential directives, national strategies, and Federal Government plans and guidance. In addition, internal emergency plans and procedures augment the FDA EOP and provide specific guidance to agency personnel during emergencies and disasters. These documents are listed chronologically by category and summarized below.⁴⁵

Authorities and references specific to individual hazards are also included in the FDA EOP Incident Annexes.

F.1 STATUTES AND REGULATIONS

F.1.1 Federal Food, Drug, and Cosmetic Act

FDA's mission is mandated by the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act), 21 U.S.C. § 301, as amended (www.fda.gov/opacom/laws/fdact/fdctoc.htm). The following FD&C Act provisions govern FDA emergency actions:

- a. In consultation with experts in science, medicine, and public health and, in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products, FDA is charged with (1) promoting the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner, and (2) with respect to such products, protecting the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled; the public health and safety are protected from electronic product radiation; and tobacco products are properly labeled and are not contaminated.
- b. FDA is charged with ensuring that safe and effective drugs, biologics, and devices are available for emergency use.
- c. If FDA finds a reasonable possibility that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the agency can order that distribution of any such tobacco product immediately cease and can order a recall as necessary. FDA may also provide notice to persons subject to the risks associated with the use of such tobacco product.
- d. If FDA determines that a tobacco product presents an unreasonable risk of substantial harm to the public health, the agency can provide notice to the public as necessary to eliminate such risk, including issuing public service announcements.
- e. FDA is authorized to inspect the records of each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products if the agency has a reasonable belief that a tobacco product is part of illicit trade, smuggling, or counterfeiting operations.
- f. The Commissioner of Food and Drugs or designee may request a firm to initiate a recall when a product has been distributed that presents a risk of illness or injury or gross consumer deception; when the responsible firm has not initiated a recall of the product; and when an agency action is necessary to protect the public health and welfare. A request by FDA that a firm recall a product is

⁴⁵ This list is not exhaustive, and the associated summaries should not be used as a substitute for the authorities and references themselves.

reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

- g. Under the Project BioShield Act of 2004 (P.L. 108-276), the FD&C Act is amended to allow FDA, in response to a declaration issued by the HHS Secretary, to authorize the use, with appropriate safeguards, of unapproved drugs, devices, or biological products or the use of approved products for unapproved uses. Before FDA can issue an EUA, the HHS Secretary must declare an emergency justifying the authorization to use the product, based on one of three determinations: (1) a determination by the Secretary of Homeland Security of a domestic emergency, or the significant potential for a domestic emergency; (2) a determination by the Secretary of Defense of a military emergency, or the significant potential for a military emergency; or (3) a determination by the HHS Secretary of a public health emergency under PHSA.
- h. The Pandemic and All-Hazards Preparedness Act (P.L. 109-417), December 2006, amends the FD&C Act to direct FDA to establish a team of experts on manufacturing and regulatory activities (including compliance with current GMP) to provide both offsite and onsite technical assistance to the manufacturers of qualified countermeasures, security countermeasures, or vaccines at the request of such a manufacturer and at the discretion of the Secretary, if the Secretary determines that a shortage or potential shortage may occur in the United States in the supply of such vaccines or countermeasures and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.

The Food Safety Modernization Act of 2011 (FSMA) (P.L. 111-353) amends the FD&C Act as follows:

- a. If FDA reasonably believes an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article must permit FDA to have access to and copy certain records relating to such article and to any other article of food the Secretary reasonably believes is likely to be affected in a similar manner.
- b. If FDA believes there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article must permit FDA to have access to and copy certain records relating to such article and to any other article of food the Secretary reasonably believes is likely to be affected in a similar manner.
- c. FDA may order the detention of any article of food that is found during an inspection, examination, or investigation if FDA has reason to believe that such article is adulterated or misbranded.
- d. If FDA determines there is a reasonable probability that an article of food (other than infant formula) is adulterated under Section 402 of the FD&C Act or misbranded under Section 403 of the FD&C Act and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary must provide the responsible party with an opportunity to cease distribution and recall such article. If the responsible party refuses to or does not voluntarily cease distribution or recall such article within the time and in the manner prescribed by the Secretary, the Secretary may, by order, require such person to (A) immediately cease distribution of such article; and (B) as applicable, immediately notify all persons – (i) manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and (ii) to which such article has been distributed, transported, or sold, to immediately cease distribution of such article.

- e. Food facilities must report to FDA as soon as practicable, but in no case later than 24 hours, within determining there is a reasonable probability that the use of, or exposure to, an article of food manufactured, processed, packed, or held at the facility will cause serious adverse health consequences or death to humans or animals.
- f. If FDA determines that food manufactured, processed, packed, received, or held by a facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may suspend the registration of a facility that was responsible for such reasonable probability or knew, or had reason to know of, such reasonable probability and packed, received, or held such food. If a facility's registration is suspended, no person can introduce food from such facility into interstate or intrastate commerce in the United States.

F.1.2 Public Health Service Act

The Public Health Service Act (PHSA), Title XXVIII: National Preparedness for Bioterrorism and Other Public Health Emergencies, as amended, charges FDA with assisting the Secretary, other HHS OPDIVs, and Federal and SLTT government partners in response to bioterrorism and other public health emergencies (www.fda.gov/regulatoryinformation/legislation/ucm148717.htm).

F.1.3 Federal Anti-Tampering Act

The Federal Anti-Tampering Act (FATA), 18 U.S.C. 1365, authorizes FDA to investigate any tampering of FDA-regulated consumer products (www.fda.gov/RegulatoryInformation/Legislation/ucm148785.htm).

F.1.4 Bioterrorism Act

FDA is responsible for carrying out certain provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) (P.L. 107-188) (www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm).

Particularly, Subtitle A (Protection of Food Supply) and Subtitle B (Protection of Drug Supply) of Title III provide for the following FDA authorizations:

- FDA may detain any article of food found during an inspection, examination, or investigation that presents a threat of serious adverse health consequences or death to humans or animals.
- FDA is authorized to access certain records when there is a reasonable belief that an article of food is adulterated and presents a threat of adverse health consequences or death to humans or animals.
- Owners and operators of foreign or domestic food facilities that manufacture or process, pack, or hold food for human or animal consumption in the United States must submit information (i.e., identity of the food, manufacturer and shipper, grower, country of origin, country from which the food is shipped, and anticipated port of arrival) to FDA about the facility and emergency contacts.
- FDA shall receive prior notice of imported food shipments before the food arrives at any U.S. port, which must include the article, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of arrival, and conduct a bioterrorism risk assessment.
- FDA is charged with providing for research on tests and sampling methodologies designed to test food to detect adulteration rapidly, particularly methodologies that detect intentional adulteration and tests that are suitable for inspections of food at ports of entry to the United States.
- FDA is authorized to conduct examinations and investigations through the officers and employees of another Federal Department or Agency, pursuant to an MOU, at facilities or other locations that are jointly regulated by FDA and such Department or Agency. FDA is required to notify States

when there is credible evidence or information indicating that a shipment, or portions of a shipment, of imported food presents a threat of serious adverse health consequences or death to humans or animals.

- Another Federal Department's or Agency's officers and employees are authorized to conduct examinations and investigations on FDA's behalf, pursuant to the signing of an MOU between FDA and the head of the other Federal Agency.
- FDA, in direct coordination with the CDC and USDA, is charged with coordinating the surveillance of zoonotic diseases.

F.1.5 Stafford Act

The Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), P.L. 93-288 (1988), as amended, codified at 42 U.S.C. §§ 68 (2007), describes the programs and processes by which the Federal Government provides disaster and emergency assistance to State and local governments, tribal nations, eligible private nonprofit organizations, and individuals affected by a declared emergency or major disaster. The Stafford Act covers all hazards, including natural disasters and terrorist events (www.fema.gov/pdf/about/stafford_act.pdf).

F.1.6 Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act of 2005 (PREP Act) (P.L. 109-148), PHSA § 319F-4, authorizes the Secretary to issue a declaration to provide immunity from tort liability for certain claims that are causally related to development, distribution, administration, or use of "covered countermeasures" and authorizes an emergency fund in the U.S. Department of the Treasury for compensation for injuries from covered countermeasures (www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx).

F.1.7 Title 18 and Title 21 United States Code

FDA investigative jurisdiction includes the FD&C Act and other related Acts (Title 21 U.S.C. and related Acts); FATA (Title 18 U.S.C. § 1365); and related violations of Title 18 U.S.C. (www.fda.gov/ICECI/CriminalInvestigations/ucm123030.htm).

F.1.8 Code of Federal Regulations Title 21

Title 21, Chapter I, is the portion of the CFR that governs FDA-regulated products within the United States for FDA. The regulations described within Chapter I of CFR 21 are enforced by FDA, based on the FD&C Act and other applicable laws (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm).

F.2 PRESIDENTIAL DIRECTIVES

The following presidential directives mandate action from all Federal Departments and Agencies, including FDA as an HHS OPDIV.

F.2.1 PPD-8, National Preparedness

Presidential Policy Directive 8 (PPD-8), *National Preparedness* requires the development of a national preparedness goal and national preparedness system. PPD-8 is designed to facilitate an integrated, all-of-Nation/whole community, capabilities-based approach to preparedness.

PPD-8 replaces Homeland Security Presidential Directive-8 (HSPD-8), *National Preparedness* and HSPD-8 Annex I, *National Planning*, which are rescinded, except for paragraph 44 of HSPD-8 Annex I. Individual plans developed under HSPD-8 and HSPD-8 Annex I remain in effect until rescinded or otherwise replaced (www.dhs.gov/presidential-policy-directive-8-national-preparedness).

F.2.2 National Preparedness Goal

The NPG sets the vision for nationwide preparedness and identifies the core capabilities and targets necessary to achieve preparedness across five mission areas laid out under PPD-8: **Prevention, Protection, Mitigation, Response, and Recovery** (www.fema.gov/learn-about-presidential-policy-directive-8).

F.2.3 National Preparedness System

The National Preparedness System is an integrated set of guidance, programs, and processes, enabling the Nation to meet the NPG. Designed to guide domestic efforts of all levels of Government, the private and nonprofit sectors, and the public, the National Preparedness System includes guidance for planning, organization, equipment, training, and exercises needed to build and maintain domestic capabilities in support of the NPG (www.fema.gov/learn-about-presidential-policy-directive-8).

F.2.4 National Planning Frameworks

The National Planning Frameworks, which are part of the National Preparedness System, set the strategy and doctrine for building, sustaining, and delivering the core capabilities identified in the NPG. They describe the coordinating structures and alignment of key roles and responsibilities for the whole community and are integrated to ensure interoperability across all mission areas (www.fema.gov/learn-about-presidential-policy-directive-8).

There is one framework for each of the five preparedness mission areas addressed in PPD-8:

- *National Prevention Framework*
- *National Protection Framework*
- *National Mitigation Framework*
- *National Response Framework* (second edition)
- *National Disaster Recovery Framework*

F.2.5 HSPD-5, Management of Domestic Incidents

HSPD-5 requires the Secretary of Homeland Security to develop and administer a national incident management system that will provide a consistent nationwide approach for Federal, State, and local governments to work effectively and efficiently together to prepare for, respond to, and recover from domestic incidents, regardless of cause, size, or complexity. HSPD-5 also requires the Secretary of Homeland Security, after consultation with appropriate Federal officials, to develop and administer a National Response Plan (NRP). The Directive orders the heads of all Federal Agencies to adopt NIMS and NRP and to provide assistance to the Secretary in their development and maintenance (www.dhs.gov/laws-regulations-1).

F.2.6 HSPD-7, Critical Infrastructure Identification, Prioritization, and Protection

HSPD-7 establishes a national policy for Federal Agencies to identify and prioritize U.S. critical infrastructure and key resources and to protect them from terrorist attacks (www.dhs.gov/xabout/laws/gc_1214597989952.shtm).

F.2.7 HSPD-9, Defense of United States Agriculture and Food

HSPD-9 establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies (www.phe.gov/s3/legal/Pages/executive.aspx).

F.2.8 HSPD-10, Biodefense for the 21st Century

HSPD-10 establishes strategies for preventing, protecting against, and mitigating biological weapons attacks perpetrated against homeland and global interests (www.phe.gov/s3/legal/Pages/executive.aspx).

F.2.9 HSPD-18, Medical Countermeasures Against Weapons of Mass Destruction

HSPD-18 establishes an approach for the development and acquisition of medical countermeasures for attacks involving CBRN agents (www.phe.gov/s3/legal/Pages/executive.aspx).

F.2.10 NSPD-51/HSPD-20, National Continuity Policy

This directive, also known as National Security Presidential Directive 51 (NSPD-51), establishes a comprehensive national policy on the continuity of Federal Government structures and operations and a single National Continuity Coordinator responsible for coordinating the development and implementation of Federal continuity policies (www.fema.gov/guidance-directives).

F.2.11 HSPD-21, Public Health and Medical Preparedness

HSPD-21 establishes a national strategy that will enable a level of public health and medical preparedness sufficient to address a range of possible disasters (www.phe.gov/s3/legal/Pages/executive.aspx).

F.2.12 HSPD-22, Domestic Chemical Defense

HSPD-22 establishes a national policy and directs actions to strengthen the ability of the United States to prevent, protect, respond to, and recover from terrorist attacks employing toxic chemicals and other chemical incidents. (This directive is classified and, thus, not publicly available.)

F.3 NATIONAL STRATEGIES

F.3.1 National Strategy for the Physical Protection of Critical Infrastructures and Key Assets

The *National Strategy for the Physical Protection of Critical Infrastructures and Key Assets* establishes a foundation for building and fostering the cooperative environment in which Government, industry, and private citizens can carry out their respective protection responsibilities more effectively and efficiently. Moreover, this Strategy identifies a clear set of national goals and objectives and outlines the guiding principles that underpin the efforts to secure the infrastructures and assets vital to national security, governance, public health and safety, economy, and public confidence (www.dhs.gov/national-strategy-physical-protection-critical-infrastructure-and-key-assets *National Strategy for Physical Protection of Critical Infrastructure and Key Assets / Homeland Security*).

F.3.2 National Strategy for Homeland Security

The *National Strategy for Homeland Security* guides, organizes, and unifies the Nation's homeland security efforts. Homeland security is a responsibility shared across the entire Nation, and the Strategy provides a common framework to prevent and disrupt terrorist attacks; protect the American people, critical infrastructure, and key resources; respond to and recover from incidents that do occur; and continue to strengthen the foundation to ensure long-term success. It builds upon the 2002 version; reflects an increased understanding of the terrorist threats confronting the United States today; incorporates lessons learned from exercises and real-world catastrophes, including Hurricane Katrina; and proposes new initiatives and approaches that will enable the Nation to achieve its homeland security objectives (www.dhs.gov/xabout/history/gc_1193938363680.shtm).

F.3.3 National Security Strategy

The *National Security Strategy* guides, organizes, and unifies our Nation's homeland security efforts and lays out a strategic approach for advancing American interests, including the security of the American people, a growing U.S. economy, support for our values, and an international order that can address 21st century challenges (www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf).

F.4 FEDERAL PLANS AND GUIDANCE

F.4.1 Comprehensive Preparedness Guide 101

The *Comprehensive Preparedness Guide (CPG) 101: Developing and Maintaining Emergency Operations Plans* expands on FEMA's efforts to provide guidance about response and recovery planning to SLTT governments. It also extends those planning concepts into the prevention and protection mission areas. CPG 101 integrates concepts from the *National Preparedness Guidelines*, NIMS, NRF, *National Strategy for Information Sharing (NSIS)*, and *National Infrastructure Protection Plan (NIPP)*, and it incorporates recommendations from the 2005 *Nationwide Plan Review* (www.fema.gov/about/divisions/cpg.shtm).

F.4.2 National Incident Management System

NIMS provides a systematic, proactive approach to guide Departments and Agencies at all levels of Government, NGOs, and the private sector to work seamlessly to prevent, protect against, respond to, recover from, and mitigate the effects of incidents, regardless of cause, size, location, or complexity, to reduce the loss of life and property and harm to the environment. NIMS works hand-in-hand with the NRF. It provides the template for the management of incidents, while the NRF provides the structure and mechanisms for national-level policy for incident management.

NIMS is not an operational incident management or resource allocation plan. It represents a core set of doctrines, concepts, principles, terminology, and organizational processes that enable effective, efficient, and collaborative incident management (www.fema.gov/emergency/nims).

NIMS has established ICS as the standardized incident organizational structure for the management of all incidents.

F.4.3 National Infrastructure Protection Plan

NIPP, and its supporting Sector-Specific Plans (SSPs), provide a coordinated approach to critical infrastructure and key resources (CIKR) protection roles and responsibilities for Federal and SLTT government and private sector security partners. NIPP sets national priorities, goals, and requirements for effective distribution of funding and resources, which help ensure the Nation's Government, economy, and public services continue in the event of a terrorist attack or other disaster (www.dhs.gov/xlibrary/assets/NIPP_Plan_noApps.pdf).

The SSPs provide the means by which the NIPP is implemented across all 18 CIKR sectors, as well as a national framework for each sector to address its unique characteristics and risk landscape. FDA is responsible for the food sector (except meat; poultry; and frozen, dried, and liquid eggs, which are under the authority of the USDA/FSIS). Agency food sector protection efforts are detailed in the Agriculture and Food CIKR SSP to the NIPP (www.fda.gov/downloads/Food/FoodDefense/ucm081308.pdf). FDA also supports HHS, which is responsible for the SSP for the public health and medical sector.

F.4.4 National Preparedness Guidelines

The *National Preparedness Guidelines* organizes and synchronizes national (including Federal and SLTT) efforts to strengthen preparedness. The *Guidelines* guide national investments in national preparedness, incorporate lessons learned from past emergencies and disasters into national preparedness priorities, facilitate a capability- and risk-based investment planning process, and establish readiness metrics to measure progress and a system for assessing the Nation's overall preparedness capability to respond to major events, especially those involving acts of terrorism. There are four critical elements to the *Guidelines*: (1) the *National Preparedness Vision*; (2) the 15 *National Planning Scenarios*; (3) the

Universal Task List (UTL); and (4) the *Target Capabilities List (TCL)* (www.dhs.gov/national-preparedness-guidelines).

F.4.5 National Response Framework

The NRF presents the guiding principles that enable first responders, decision makers, and supporting entities to prepare for and provide a unified national response to emergencies and major disasters—from the smallest incident to the largest catastrophe. It establishes a comprehensive, national, all-hazards approach to domestic incident management and defines the key principles, roles, and structures that organize the way the Nation responds.

The NRF, an update to the 2004 NRP, describes how communities, tribes, territories, States, the Federal Government, and private sector and nongovernmental partners apply these principles for a coordinated, effective national response. This document also identifies special circumstances where the Federal Government exercises a larger role, including incidents where Federal interests are involved and catastrophic incidents where a State would require significant support. The NRF enables first responders, decision makers, and supporting entities to provide a unified national response (www.fema.gov/emergency/nrf).

F.4.6 National Disaster Recovery Framework

The *NDRF* is a guide that enables effective recovery support to disaster-impacted SLTT jurisdictions. It provides a flexible structure that enables disaster recovery managers to operate in a unified and collaborative manner. It also focuses on how best to restore, redevelop, and revitalize the health, social, economic, natural, and environmental fabric of the community and build a more resilient Nation.

The NDRF is consistent with the vision set forth in *PPD-8, National Preparedness*, which directs FEMA to work with interagency partners to publish a recovery framework.

The NDRF introduces six new *Recovery Support Functions* that provide a structure to facilitate problem-solving, improve access to resources, and foster coordination among State and Federal agencies, nongovernmental partners, and stakeholders. Each RSF has coordinating and primary Federal Agencies and supporting organizations that operate together with State, local, and tribal government officials, NGOs, and private sector partners.

The NDRF presents three positions that provide focal points for incorporating recovery considerations into the decision-making process and monitoring the need for adjustments in assistance where necessary and feasible throughout the recovery process. Those positions are Federal Disaster Recovery Coordinator (FDRC), State or Tribal Disaster Recovery Coordinators (SDRCs or TDRCs), and Local Disaster Recovery Managers (LDRMs) (www.fema.gov/national-disaster-recovery-framework).

F.5 HHS PLANS

HHS plan(s) that guide FDA emergency operations include the following:

- *HHS All-Hazards Plan* (Document Version 8, September 2012). This plan provides a high-level view of the actions HHS can take to assist in an emergency and centralizes common steps and information needs in a single plan. HHS and other Federal or partner agencies involved in emergency planning, response, and recovery can use this plan to understand what public health and medical assistance HHS provides.

F.6 FDA SUPPORTING DOCUMENTATION

F.6.1 Center/Office Emergency Plans and Procedures

Some FDA organizational components have developed individual emergency plans and operating procedures that define the scope of incident management activities necessary for that Center or Office. These EOPs and subordinate procedural documents present specific details on Center/Office response to emergencies and disasters, such as assigning staff roles, responsibilities, and lines of authority; detailing projected times, places, and coordination mechanisms for carrying out emergency actions; describing how staffs and facilities are protected; and identifying the personnel, equipment, facilities, supplies, and other resources necessary for use during response and recovery operations.

The following represent the compendium of existing FDA emergency/disaster plans and procedures. Each supports implementation of the FDA EOP and is available to assist FDA personnel during prevention, preparedness, protection, mitigation, response, and recovery activities.

- *Regulatory Procedures Manual*, Chapter 8, “Emergency Procedures” (July 2012)
www.fda.gov/ora/compliance_ref/rpm/chapter8/ch8.html
- *Investigations Operations Manual 2013*, Chapter 8, Subchapter 8.5, “Disaster Procedures”
www.fda.gov/ora/inspect_ref/iom
- *FDA Incident Management Handbook* (September 2013). This handbook is designed to assist FDA personnel in the use of ICS and NIMS during incident response operations and planned events. The handbook is an easy reference job aid for responders and includes position-specific checklists. The handbook provides guidance and protocols for responders and management to understand what their positional responsibilities are under ICS/NIMS and how these positions integrate with the overall response structure.
- *FDA Joint Information Center Handbook* (November 2013). This handbook is for personnel assigned to a FDA JIC as part of an IMG incident response or planned event. The handbook describes the organization of FDA personnel tasked with public information responsibilities. The handbook provides an organized approach to providing accurate, coordinated, timely, and accessible information to FDA audiences as an emergency situation evolves.
- *Continuity of Operations (COOP) Plan for the Office of the Commissioner* (January 2013)

Copies of individual Center and Office emergency plans and procedures may be found on the Center/Office intranet Web pages on [inside.fda](#).



F.6.2 SOP for FDA Headquarters Building Closures and Dismissal of Employees

The current operational status of FDA headquarters' buildings and dismissal of employees related to administrative situations including all FDA locations in the Washington, D.C., metropolitan area, including the White Oak Campus, is provided at www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/default.htm.

F.6.3 Center/Office COOP Plans

FDA has designed COOP Plans for each of its headquarters and field organizational components, including OC, ORA, CBER, CDER, CDRH, CFSAN, CVM, and the Regional and District offices. These plans ensure that agency essential functions can continue to be performed from alternate locations during all hazards, including localized acts of nature, accidents, and technological or attack-related situations.



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G. PLAN MANAGEMENT

G.1 COORDINATION

The FDA OCM is responsible for the overall management and maintenance of the FDA EOP (including all annexes and appendices) and for ensuring that changes and revisions occur, including their preparation, coordination, publication, and distribution. OCM, in consultation with all responsible agency Centers and Offices, coordinates plan reviews to address lessons learned from real-world and simulated incidents and incorporates necessary organizational or technological changes.

G.2 MAINTENANCE

Any FDA headquarters or field organizational component may propose changes to the FDA EOP. All proposed changes are to be captured within the “Record of Changes” section to this EOP and submitted to OCM for formal review. Approval from the appropriate Center/Office senior official should be secured prior to submitting any proposed change.

Once OCM receives a proposed change to the FDA EOP, it will coordinate a review with all applicable Centers and Offices to determine its suitability for inclusion in the plan. Once this coordination has been finalized, OCM will issue an official Notice of Change agency-wide and provide the intra- and Internet links to the updated plan.

- The Notice of Change will specify the date, number, subject, purpose, background, and action required, and provide the change language.
- Once published, the changes will be considered part of the FDA EOP for operational purposes pending a formal revision and re-issuance of the entire document.

G.3 PROMULGATION

The OCM Director is responsible for coordinating reviews of the basic plan and all applicable annexes to the FDA EOP and for re-adoption and distribution every 4 years or more frequently as deemed necessary. The annual review will consider lessons learned and best practices identified during exercises and/or actual emergencies and disasters. Any changes that result from reviews will be incorporated in the FDA EOP and any supporting Center/Office emergency plans and procedures.

Prior to any reissuance of the EOP, or at the request of the Commissioner or his/her authorized representative, OCM will work with agency headquarters and field emergency coordinators and others as appropriate to revise key areas of the plan. OCM will disseminate the final draft of the revised FDA EOP for review and concurrence prior to submitting to the Commissioner for approval and promulgation.

G.4 STANDARDS FOR SUPPORTING DOCUMENTATION

The FDA EOP, including the basic plan and all annexes, is the core plan for FDA emergency operations and provides the structures and processes for coordinating agency incident management activities for emergencies, including natural disasters, terrorist attacks, and other criminal acts. It provides an umbrella configuration for existing emergency plans and procedural documents (with appropriate modifications and revisions) as integrated components, supplements, or supporting material.

All FDA organizational components must incorporate common principles, concepts, and language when developing or updating individual emergency plans and procedures. Accordingly, all Center/Office emergency documentation shall be compatible with the FDA EOP.

G.5 TRAINING AND EXERCISES

FDA shall conduct and/or participate in HHS and other organizations' tests, training, and exercises to ensure that agency personnel are familiar with assigned emergency roles and responsibilities and that the FDA EOP can be implemented rapidly and effectively.

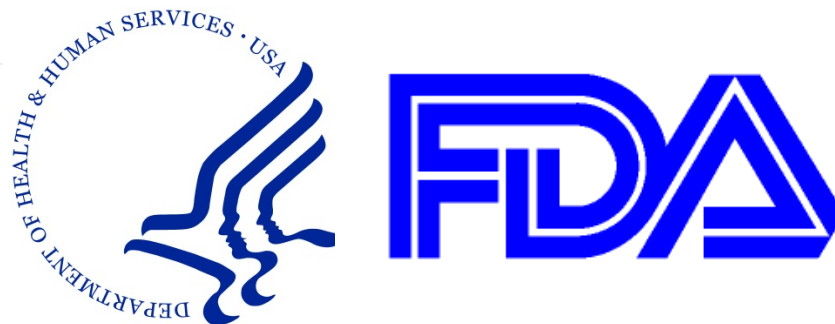
Any deficiencies, findings, areas recommended for corrective action, or improvements arising from exercises will be addressed through additional training, plan updates, and/or demonstrations in subsequent emergency preparedness events.

G.6 IMPLEMENTATION

The FDA EOP, including the basic plan and all annexes, is effective for execution upon and pursuant to approval by the Commissioner.

OCM shall ensure this FDA EOP is subject to regular maintenance, review, and updates based on organizational and procedural changes, AARs, and new guidance. At any time, agency emergency coordinators, upon approval by the Center/Office senior official, should recommend to OCM improvements and changes thereto that are appropriate. The FDA EOP and any approved changes will be forwarded to all organizational components with responsibilities for implementation of the plan.

The FDA EOP shall be placed on the FDA intranet ([inside.fda](#)) and Internet (www.fda.gov) websites and updated as changes occur.



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. Food and Drug Administration**

Appendices to the FDA Emergency Operations Plan

Version 2.0

March 2014

OFFICE OF CRISIS MANAGEMENT

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APPENDICES TABLE OF CONTENTS

Appendix A: FDA Support for the Emergency Support Function Annexes to the National Response Framework.....	App A-1
A.1 ESF #8 – Public Health and Medical Services.....	App A-1
A.2 ESF #10 – Oil and Hazardous Materials Response	App A-4
A.3 ESF #11 – Agriculture and Natural Resources	App A-5
Appendix B: FDA Support for the Incident Annexes to the NRF	App B-1
B.1 Biological Incident Annex	App B-1
B.2 Catastrophic Incident Annex	App B-2
B.3 Food and Agriculture Incident Annex	App B-3
B.4 Nuclear/Radiological Incident Annex	App B-5
B.5 Terrorism Incident Law Enforcement and Investigation Annex	App B-6
Appendix C: Processing Mission Assignment Sub-Taskings	App C-1
C.1 Purpose	App C-1
C.2 Assumptions.....	App C-1
C.3 Scope	App C-1
C.4 Procedure.....	App C-2
C.4.1 Processing Action Request Form	App C-2
C.4.1.1 FDA/State Coordination	App C-2
C.4.1.1 Initial FDA Internal Coordination (Field and Headquarters).....	App C-3
C.4.2 Processing a Mission Assignment Sub-Task.....	App C-3
C.4.2.1 FDA/FEMA/HHS Coordination.....	App C-3
C.4.2.2 FDA Internal Coordination	App C-4
C.4.2.3 MA Monitoring and Closeout	App C-4
Attachment C-1: FDA Pre-Scripted Mission Assignments.....	App C-1-1
Attachment C-2: ARF for FDA Retail Food Establishment Inspections Sample....	App C-2-1
Attachment C-3: MA Form Based On Completed ARF Sample.....	App C-3-1
Attachment C-4: Stafford Act Mission Sub-Tasking Based on MA Form Sample .	App C-4-1
Appendix D: Characteristics of Potential Foodborne Agents.....	App D-1
Appendix E: Chemical Agents – Background Information	App E-1
E.1 General Information	App E-1
E.2 Classes of Chemical Warfare Agents	App E-1
E.3 Nerve Agent Exposure Versus Nerve Agent Intoxication	App E-2
E.4 Chemical Agent Characteristics.....	App E-3
E.5 List of Additional Chemical Agents.....	App E-4
Appendix F: Biological Agents – Background Information	App F-1
F.1 General Information	App F-1
F.2 Classes of Biological Warfare Agents	App F-1
F.3 Epidemiologic Clues That May Signal a Covert Bioterrorism Attack	App F-2
F.4 Bioterrorism Agents/Diseases By Category.....	App F-3



Appendix G: Oversight of Select Agents and Toxins by HHS/CDC and USDA/Animal and Plant Health Inspection Service	App G-1
G.1 HHS Select Agents and Toxins	App G-1
G.2 Overlap Select Agents and Toxins	App G-1
G.3 USDA Select Agents and Toxins	App G-2
G.4 USDA Plant Protection and Quarantine Select Agents and Toxins	App G-3
Appendix H: Domestic and International Traceback/Traceforward	App H-1
H.1 Domestic	App H-1
H.2 International	App H-1
Appendix I: Memorandum of Understanding	App I-1
Appendix J: Forms and Templates	App J-1
Appendix K: Glossary of Terms	App K-1
Appendix L: List of Acronyms and Abbreviations	App L-1

LIST OF FIGURES

Figure C-1. Process Overview	App C-2
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Appendix A:

FDA Support for the Emergency Support Function Annexes to the National Response Framework

The Emergency Support Function (ESF) annexes to the *National Response Framework* (NRF) provide the structure for coordinating Federal interagency support for a Federal response to an incident. They are mechanisms for grouping functions most frequently used to provide Federal support to States and Federal-to-Federal support, both for declared disasters and emergencies under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) and for non-Stafford Act incidents.

The ESF annexes are used by both Federal and State governments as the primary mechanism at the operational level to organize and provide assistance. ESFs align categories of resources and provide strategic objectives for their use. ESFs use standardized resource management concepts such as typing, inventorying, and tracking to facilitate the dispatch, deployment, and recovery of resources before, during, and after an incident.

Depending on the nature of the emergency, the U.S. Food and Drug Administration's (FDA's) emergency response roles and responsibilities may fall under one or more of the following ESFs.

A.1 ESF #8 – PUBLIC HEALTH AND MEDICAL SERVICES

The ESF #8 – Public Health and Medical Services Annex¹ provides the mechanism for Federal assistance to supplement State, local, tribal, and territorial (SLTT) and insular area resources in response to a disaster, emergency, or incident that may lead to a public health, medical, behavioral, or human service emergency, including those that have international implications.

Primary Agency

- U.S. Department of Health and Human Services (HHS)

ESF Coordinator

- HHS

Scope

ESF #8 provides supplemental assistance to SLTT and insular area governments in the following core functional areas:

- Assessment of public health/medical needs
- Health surveillance
- Medical surge
- Health/medical/veterinary equipment and supplies
- Patient movement
- Patient care
- Safety and security of drugs, biologics, and medical devices
- Blood and tissues
- Food safety and defense
- Agriculture safety and security
- All-hazards public health and medical consultation, technical assistance, and support
- Behavioral healthcare

¹ For more information on ESF #8, refer to www.fema.gov/media-library/assets/documents/32198?id=7359.

- Public health and medical information
- Vector control
- Guidance on potable water/wastewater and solid waste disposal
- Mass fatality management, victim identification, and decontaminating remains
- Veterinary medical support

Core Capabilities and Actions

The following table lists the response core capabilities that ESF #8 most directly supports along with the related ESF #8 actions.

Table A-1. ESF Roles Aligned to Core Capabilities

Core Capability	ESF #8 Public Health and Medical Services
Public Information and Warning	<ul style="list-style-type: none"> ▪ Coordinates the Federal public health and medical messaging with jurisdictional officials. ▪ Continuously acquires and assesses information on the incident. Sources of information may include State incident response authorities; officials of the responsible jurisdiction in charge of the disaster scene; and ESF #8 support departments, agencies, and organizations. ▪ Provides public health, behavioral health, disease, and injury prevention information that can be transmitted to members of the general public and responders who are located in or near affected areas in languages and formats that are understandable to individuals with limited English proficiency and individuals with disabilities and others with access and functional needs. ▪ Supports a Joint Information Center (JIC) in the release of general medical and public health response information to the public.
Public and Private Services and Resources	<p>Blood and Tissues</p> <ul style="list-style-type: none"> ▪ Monitors and ensures the safety, availability, and logistical requirements of blood and tissues. This includes the ability of the existing supply chain resources to meet the manufacturing, testing, storage, and distribution of these products. <p>Food Safety, Security, and Defense</p> <ul style="list-style-type: none"> ▪ In coordination with ESF #11, may task HHS components and request assistance from other ESF #8 partner organizations to ensure the safety, security, and defense of federally regulated foods. <p>Agriculture Safety and Security</p> <ul style="list-style-type: none"> ▪ In coordination with ESF #11, may task ESF #8 components to ensure the health, safety, and security of food-producing animals, animal feed, and therapeutics. ESF #8 may also provide veterinary assistance to ESF #11. Support will include the amelioration of zoonotic disease and caring for research animals where ESF #11 does not have the requisite expertise to render appropriate assistance.
Public Health and Medical Services	<p>Safety and Security of Drugs, Biologics, and Medical Devices</p> <ul style="list-style-type: none"> ▪ During response, provides advice to private industry regarding the safety and efficacy of drugs; biologics (including blood, tissues, and vaccines); medical devices (including radiation emitting and screening devices); and other products that may have been compromised during an incident and are HHS-regulated products. <p>All-Hazard Public Health and Medical Consultation, Technical Assistance, and Support</p> <ul style="list-style-type: none"> ▪ Providing advice on protective actions related to direct human and animal exposures and on indirect exposure through contaminated food, drugs, water supply, and other media. <p>Public Health Aspects of Potable Water/Wastewater and Solid Waste</p> <ul style="list-style-type: none"> ▪ Assists in assessing potable water, wastewater, solid waste disposal, and other environmental health issues related to public health in establishments holding, preparing, and/or serving food, drugs, or medical devices at retail and medical facilities, as well as examining and responding to public health effects from contaminated water; conducting field investigations, including collection and laboratory analysis of relevant samples; providing equipment and supplies as needed; and providing technical assistance and consultation.



Agency Actions

FDA will provide support, personnel, or expertise to HHS for many of the HHS responsibilities listed below. FDA will also:

- Monitor blood and tissue supplies, shortages, and reserves.
- Ensure the safety and security of food in coordination with other responsible Federal Agencies (e.g., U.S. Department of Agriculture [USDA]). In cooperation with SLTT and insular area officials, assesses whether food manufacturing, food processing, food distribution, food service, and food retail establishments in the affected area are able to provide safe food.
- In cooperation with SLTT and insular area officials as well as the food industry, conducts tracebacks and/or recalls of adulterated products.
- In cooperation with SLTT, insular area, and Federal officials, provides guidance regarding the proper disposal of contaminated products and the decontamination of affected food facilities in order to protect public health.
- Provides public health risk communication messages and advisories that communicate, in a culturally and linguistically appropriate and accessible manner, relevant information on health hazards or other situations that could potentially threaten public health.
- Disseminates public health information on protective actions related to exposure to health threats or environmental threats.
- Notifies or responds to foreign country potential health threats as required by International Health Regulations (IHR).
- Provides support for public health matters for radiological incidents as a member of the Advisory Team for Environment, Food, and Health.
- Consults public health and medical subject matter experts (SMEs) with ESF #8 supporting organizations (including partners representing all appropriate populations such as pediatric populations, populations with disabilities and others with access and functional needs, the aging, and those with temporary or chronic medical conditions).

A.2 ESF #10 – OIL AND HAZARDOUS MATERIALS RESPONSE

The ESF #10 – Oil and Hazardous Materials Response Annex² provides Federal support in response to an actual or potential discharge and/or release of oil or hazardous materials (HazMat) when activated.

Primary Agencies

- U.S. Environmental Protection Agency (EPA)
- U.S. Department of Homeland Security (DHS)/U.S. Coast Guard (USCG)

ESF Coordinator

- EPA

Scope

ESF #10 may be activated as described in the NRF for a Stafford Act response, at the Secretary of Homeland Security's discretion, and/or in response to a request for Federal-to-Federal support. Federal response to oil or HazMat incidents may also be carried out under another key Federal response authority called the *National Oil and Hazardous Substances Pollution Contingency Plan (NCP)*,³ a regulation with the force of law found at 40 Code of Federal Regulations (CFR) Part 300. The NCP is an operational supplement to the NRF. The NCP may be used in conjunction with, or independent from, the Stafford Act.

The scope of ESF #10 includes the appropriate actions to prepare for and respond to a threat to public health, welfare, or the environment caused by actual or potential oil and HazMat incidents.

HHS Actions

HHS directly supports ESF #10 with the following action:

- **FDA:** Works in cooperation with EPA and USDA to ensure the proper disposal of contaminated food or animal feed.

² For more information on ESF #10, refer to www.fema.gov/media-library/assets/documents/32241?id=7376.

³ For more information on the NCP, refer to www.epa.gov/OEM/content/lawsregs/ncpover.htm.

A.3 ESF #11 – AGRICULTURE AND NATURAL RESOURCES

The ESF #11 – Agriculture and Natural Resources Annex⁴ organizes and coordinates Federal support for the protection of the Nation’s agricultural and natural and cultural resources during national emergencies. ESF #11 works during actual and potential incidents to provide nutrition assistance; respond to animal and agricultural health issues; provide technical expertise, coordination, and support of animal and agricultural emergency management; ensure the safety and defense of the Nation’s supply of meat, poultry, and processed egg products; and ensure the protection of natural and cultural resources and historic properties.

Primary Agencies

- USDA
- U.S. Department of the Interior (DOI)

ESF Coordinator

- USDA

HHS Functions

This section describes specific functions performed by HHS as an ESF #11 support agency:

- HHS National Veterinary Response Teams, veterinary officers of the Commissioned Corps of the U.S. Public Health Service (USPHS), and other veterinary medical professionals within its divisions (such as the Centers for Disease Control and Prevention [CDC], FDA, and the National Institutes of Health [NIH]) is the primary Federal resource for treatment of injured and/or ill pets, service animals, working animals, laboratory animals, and livestock. Under its own statutory authority, HHS can manage and conduct animal response to zoonotic diseases in order to protect human health.
- For livestock or poultry diseases exotic to the United States that are either not or only mildly zoonotic, HHS supports the USDA and its authority to manage a foreign animal disease response with the resources listed above.

⁴ For more information on ESF #11, refer to www.fema.gov/media-library/assets/documents/32213?id=7365.



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Appendix B:

FDA Support for the Incident Annexes to the NRF

The Incident Annexes to the NRF describe the concept of operations (CONOPS) to address specific contingency or hazard situations or an element of an incident requiring specialized application of the NRF.

Depending on the nature of the emergency, FDA's response efforts support the following NRF Incident Annexes.

B.1 BIOLOGICAL INCIDENT ANNEX

Coordinating Agency

- HHS

Purpose/Scope

The NRF *Biological Incident Annex*¹ outlines the actions, roles, and responsibilities associated with a response to a human disease outbreak of known or unknown origin requiring Federal assistance. In this annex, a biological incident includes naturally occurring biological diseases (communicable and noncommunicable) in humans as well as terrorist events. This definition also includes those biological agents found in the environment, or diagnosed in animals, that have the potential for transmission to humans (zoonosis). The annex outlines biological incident response actions, including threat assessment notification procedures, laboratory testing, joint investigative/response procedures, and activities related to recovery.

The annex supports policies and procedures outlined in ESF #8, ESF #10, ESF #11, ESF #15 – External Affairs, the *Terrorism Incident Law Enforcement and Investigation Annex*, and the *International Coordination Support Annex*.

HHS serves as the Federal Government's primary Agency for the public health and medical preparation and planning for and response to a biological terrorism attack or naturally occurring outbreak that results from either a known or novel pathogen, including an emerging infectious disease.

The USDA serves as the Government's primary Agency for outbreaks and/or attacks that may occur in animals used in the commercial production of food. USDA may also serve as the Government's primary Agency for attacks on food processing, including slaughtering facilities under its regulatory purview. In the event of a food or animal event, HHS may provide additional public health and veterinary epidemiological assistance to USDA. Wildlife events will be placed under the purview of DOI, while those involving marine animals will be managed and monitored by the U.S. Department of Commerce.

HHS Responsibilities

See ESF #8 for additional information.

¹ For more information on the NRF *Biological Incident Annex*, refer to www.fema.gov/pdf/emergency/nrf/nrf_BiologicalIncidentAnnex.pdf.

B.2 CATASTROPHIC INCIDENT ANNEX

Coordinating Agency

- DHS/Federal Emergency Management Agency (FEMA)

Purpose/Scope

The *Catastrophic Incident Annex* to the NRF (NRF-CIA)² establishes the context and overarching strategy for implementing and coordinating an accelerated, proactive national response to a catastrophic incident. A catastrophic incident, as defined by the NRF, is any natural or manmade incident, including terrorism, that results in extraordinary levels of mass casualties, damage, or disruption severely affecting the population, infrastructure, environment, economy, national morale, and/or Government functions.

During a catastrophic incident, normal procedures for certain ESFs may be expedited or streamlined to address the magnitude of urgent requirements of the incident. All ESFs must explore economies of scale to maximize utilization and efficiency of limited resources.

A more detailed and operationally specific *Catastrophic Incident Supplement* to the NRF (NRF-CIS) is published independently of the NRF and its annexes.

FDA Responsibilities

Upon notification from the National Operations Center (NOC) that the NRF-CIA has been implemented, Federal Departments and Agencies immediately:

- Take actions to activate, mobilize, and deploy incident-specific resources in accordance with the NRF-CIS.
- Take actions to protect life, property, and critical infrastructure under their jurisdiction and provide assistance within the affected area.
- Commence those hazard-specific activities established under the appropriate and applicable NRF Incident Annex(es), including the NRF-CIA.
- Commence functional activities and responsibilities established under the NRF ESF annexes.
- All Federal Departments and Agencies and organizations assigned primary or supporting ESF responsibilities immediately begin implementation of those responsibilities as appropriate or when directed by the President.

² For more information on the NRF-CIA, refer to www.fema.gov/pdf/emergency/nrf/nrf_CatastrophicIncidentAnnex.pdf.

B.3 FOOD AND AGRICULTURE INCIDENT ANNEX

Coordinating Agencies

- USDA
- HHS

Purpose/Scope

The NRF *Food and Agriculture Incident Annex*³ describes the roles and responsibilities associated with all incidents involving the Nation's agriculture and food systems that require a coordinated Federal response. The objectives of a coordinated national response to an incident impacting food and agriculture are to:

- Detect the event through the reporting of illness, disease/pest surveillance, routine testing, consumer complaints, and/or environmental monitoring.
- Determine the primary coordinating agency.
- Determine the source of the incident or outbreak.
- Control and contain the distribution of the affected source.
- Identify and protect the population at risk.
- Assess public health, food, agriculture, and law enforcement implications.
- Assess the extent of residual biological, chemical, or radiological contamination, then decontaminate and dispose as necessary.

The NRF *Food and Agriculture Incident Annex* supports policies and procedures outlined in the NRF, ESF #8 – Public Health and Medical Services Annex, ESF #10 – Oil and Hazardous Materials Response Annex, ESF #11 – Agriculture and Natural Resources Annex, *Terrorism Incident Law Enforcement and Investigation Annex*, and the *Federal Food and Agriculture Decontamination and Disposal Roles and Responsibilities* document.

HHS Responsibilities

Specific responsibilities are described in greater detail in ESF #8, ESF #10, and ESF #11.

HHS provides leadership by ensuring the safety and security of food, animal feed, food-producing animals, and animal therapeutics. HHS, through the CDC and in coordination with States, develops and implements surveillance systems to monitor the health of the human population.

HHS, through FDA, has statutory authority for all domestic and imported food except meat, poultry, and egg products that are under the authority of the USDA Food Safety and Inspection Service (FSIS). FDA also has statutory authority for animal feed and for the approval of animal drugs intended for both therapeutic and nontherapeutic use in food animals as well as household pets and service animals.

³ For more information on the NRF *Food and Agriculture Incident Annex*, refer to www.fema.gov/pdf/emergency/nrf/nrf_FoodAgricultureIncidentAnnex.pdf.



FDA Responsibilities

FDA responsibilities are as follows:

- If FDA suspects a threat involving biological, chemical, or radiological agents or indications that instances of disease may not be the result of natural causes, the U.S. Department of Justice (DOJ) must be notified through the DOJ Federal Bureau of Investigation (FBI) WMD Operations Unit.
- Any potential or actual incidents requiring a coordinated Federal response involving contaminated food, infected animals or plants, or economically devastating plant pest infestation should be reported to the Secretary of Homeland Security through the NOC at 202-282-8101 and brought to the attention of designated officials according to ESF #8 and ESF #11.
- If terrorist activity is suspected in connection with the incident, procedures outlined in the *Terrorism Incident Law Enforcement and Investigation Annex* will be followed.

B.4 NUCLEAR/RADIOLOGICAL INCIDENT ANNEX

Coordinating Agencies

- U.S. Department of Defense (DoD)
- U.S. Department of Energy (DOE)
- DHS
- EPA
- National Aeronautics and Space Administration (NASA)
- U.S. Nuclear Regulatory Commission (NRC)

Purpose/Scope

The NRIA to the NRF describes the policies, situations, CONOPS, and responsibilities of the Federal Departments and Agencies governing the immediate response and short-term recovery activities for incidents involving release of radioactive materials to address the consequences of the event. These incidents may occur on Federal-owned or licensed facilities, privately owned property, urban centers, or other areas and may vary in severity from the small to the catastrophic. The incidents may result from inadvertent or deliberate acts. The NRIA applies to incidents where the nature and scope of the incident requires a Federal response to supplement the State, tribal, or local incident response.

This annex applies to two categories of nuclear and radiological incidents: (1) inadvertent or otherwise accidental releases and (2) releases related to deliberate acts. These incidents may also include potential release of radioactive material that poses an actual or perceived hazard to public health, safety, national security, and/or the environment. The category covering inadvertent releases includes: two categories of nuclear facilities (commercial or weapons production facilities), lost radioactive material sources, transportation accidents involving nuclear/radioactive material, domestic nuclear weapons accidents, and foreign accidents involving nuclear or radioactive material that impact the United States or its territories, possessions, or territorial waters. The second category includes, but is not limited to, response to the effects of deliberate attacks perpetrated with radiological dispersal devices (RDDs), nuclear weapons, or improvised nuclear devices (INDs).

This annex applies whenever a Federal response is undertaken unilaterally pursuant to Federal authorities or when an incident exceeds or is anticipated to exceed State, tribal, or local resources. The level of Federal response to a specific incident is based on numerous factors, including the ability of State, tribal, and local officials to respond; the type, amount, and custody of (or authority over) radioactive material involved; the extent of the impact or potential impact on the public and environment; and the size of the affected area.

FDA Responsibilities

FDA responsibilities are as follows:

- Provide a representative to the Advisory Team to develop coordinated advice and recommendations on environmental, food, health, and animal health matters for the Incident Command/Unified Command (UC), DHS, Joint Field Office (JFO) Unified Coordination Group, the coordinating agency, and/or State, tribal, and local government as appropriate.
- Provide laboratory capabilities for food and agriculture analysis.

B.5 TERRORISM INCIDENT LAW ENFORCEMENT AND INVESTIGATION ANNEX

Coordinating Agency

- DOJ/FBI

Purpose/Scope

The purpose of the *Terrorism Incident Law Enforcement and Investigation Annex* is to facilitate an effective Federal law enforcement and investigative response to all threats or acts of terrorism within the United States, regardless of whether they are deemed credible and/or whether they escalate to an “incident of national significance.” To accomplish this, the annex establishes a structure for a systematic, coordinated, unified, timely, and effective national law enforcement and investigative response to threats or acts of terrorism within the United States.

This annex is a strategic document that:

- Provides planning guidance and outlines operational concepts for the Federal law enforcement and investigative response to a threatened or actual terrorist incident within the United States.
- Acknowledges and outlines the unique nature of each threat or incident, the capabilities and responsibilities of the local jurisdictions, and the law enforcement and investigative activities necessary to prevent or mitigate a specific threat or incident.

FDA Responsibilities

FDA responsibilities are as follows:

- Provide support to Federal law enforcement and investigative response efforts related to threats or acts of terrorism involving or impacting FDA-regulated products.
- If terrorist activity is suspected in connection with any incident involving FDA-regulated product, the *Terrorism Incident Law Enforcement and Investigation Annex* will be followed and the Office of Criminal Investigations (OCI) should be notified of such. OCI will coordinate the terrorism incident law enforcement response with the FBI.

Appendix C: Processing Mission Assignment Sub-Taskings

C.1 PURPOSE

The purpose of this appendix is to establish a uniform procedure for the FDA to execute sub-tasks under mission assignments (MAs). The appendix supports HHS MAs under the NRF and the *National Disaster Recovery Framework* (NDRF).

FDA provides timely disaster response operating under its own authorities. In response to a catastrophic event, there are cases where DHS/FEMA will issue MAs to HHS/FDA to provide additional resources to States and local jurisdictions affected by the disaster. Types of assignments include supporting States for the inspection of retail food establishments and pharmacies, sample collection, and providing SMEs. A list of possible assignments is provided at **Attachment C-1** (FDA Pre-Scripted Mission Assignments).

MAs are addressed in the *FDA Emergency Operations Plan (EOP)* in *Section B.2.2.3.4*, “Mission Assignments in Support of State and Local Response.”

C.2 ASSUMPTIONS

Assumptions are as follows:

- MAs may be issued when the NRF or NDRF is activated as part of a Stafford Act declaration that requires a coordinated Federal response to manage a disaster and/or emergency. MAs may also be issued to HHS when Recovery Support Function (RSF) annexes are activated under the NDRF.
- The need for Federal assistance exists when the incident is of such severity and magnitude that SLTT resources are exceeded. The SLTT requests support activities outside the normal scope of FDA’s mission.
- This appendix refers only to MAs issued by FEMA to HHS and not requests for assistance from other Federal and/or SLTT agencies. The term “mission assignment” may at times be used to describe a variety of missions and tasks undertaken by FDA.
- FDA completes assignments only as MA sub-tasks issued by HHS. FDA does not sub-task other Federal Agencies. Offers of assistance from other Federal Agencies should be referred to the HHS SOC or FEMA.
- MA funds are used appropriately and expeditiously. Financial operations are conducted in accordance with established Federal law, policies, regulations, and standards to protect Federal Government resources from waste, fraud, and mismanagement.

C.3 SCOPE

This appendix applies to all FDA personnel involved in processing an HHS MA sub-task, including FDA field and headquarters staff and HHS response elements including the EMG Operations, the Human Services Watch Officer, SOC Watch Officers, and ASPR Administration and Finance (A&F).

C.4 PROCEDURE

C.4.1 Processing Action Request Form

C.4.1.1 FDA/State Coordination

While the State is responsible for determining their specific needs during a disaster, FDA field staff may assist the Region and/or State in developing language for inclusion into Action Request Forms (ARFs) if requested [see **Attachment C-2** (ARF for FDA Retail Food Establishment Inspections Sample – FEMA Form 010-0-7)]. The MA sub-task process allows FDA to be reimbursed for providing States with additional resources and assistance beyond the services and guidance provided by FDA during normal operations. **Figure C-1** provides an overview of the process.

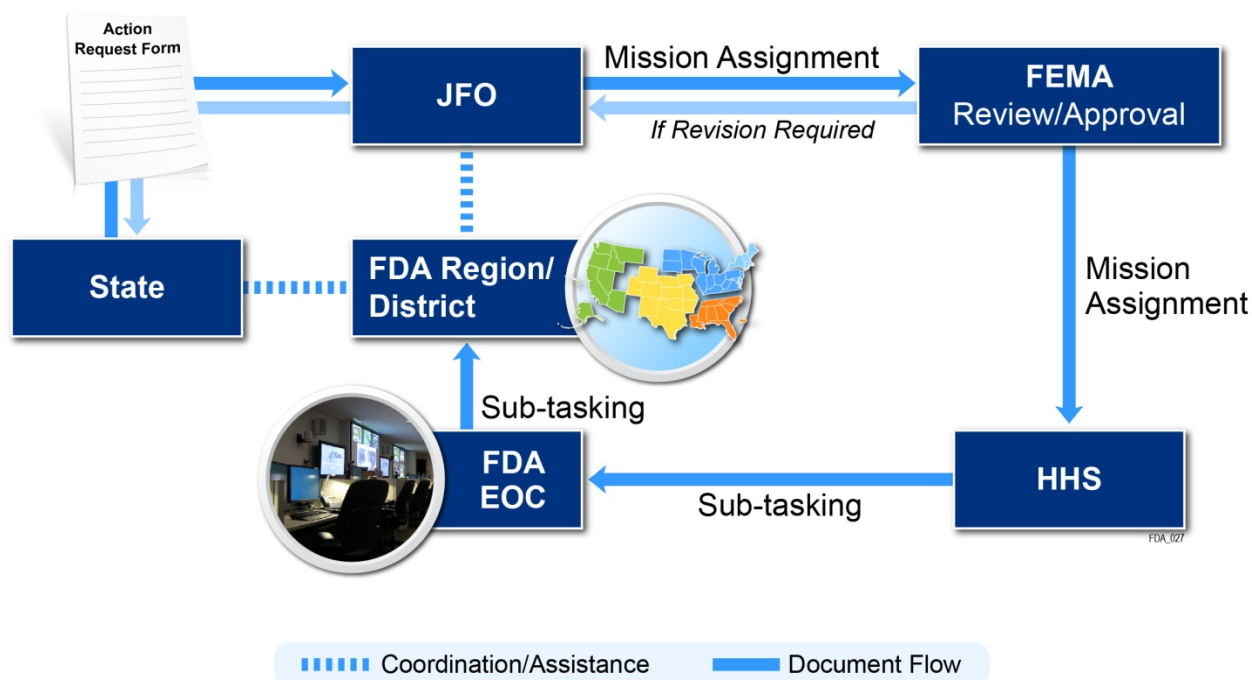


Figure C-1. Process Overview

The MA sub-task process is as follows:

1. Information exchanges with the State can be initiated by District offices on an informal basis to ensure requests are within FDA's capabilities and to facilitate coordination. To expedite this step, see **Attachment C-1** for a list of FDA Pre-Scripted Mission Assignments (PSMAs) prepared specifically for FDA as HHS MA sub-tasks. PSMAs provide examples and templates for the State to use in developing specific requests and submitting them in ARFs. See **Attachment C-2** for instructions on completing ARFs and a sample ARF.
2. Once FDA field begins discussions above with the State, the Office of Crisis Management/ Office of Emergency Operations (OCM/OEO) should be notified of a possible ARF to be submitted to FEMA.
3. During the information exchange, it may be necessary to assist the State to define requests. Specific State requirements should be identified and compared with State capabilities. If a gap is identified, appropriate FDA resources should be identified for meeting shortfalls in coordination with OCM/OEO.

4. The State is responsible for initiating, reviewing, and submitting all ARFs to FEMA for review, approval, and submission to the appropriate Department/Agency/ESF. **Attachment C-1** also provides a draft statement of work developed by FDA.
5. HHS may deploy an Incident Response Coordination Team (IRCT) to be primarily responsible for supporting the Federal public health and medical management of an incident. The IRCT provides the field management component of the Federal public health and medical response. FDA field staff will advise the IRCT as appropriate regarding the scope of any ARF. FDA may provide a liaison to the IRCT.
6. FEMA receives and reviews the ARF to determine if the request is appropriate for the specific event. If FEMA agrees, the ARF is submitted to the appropriate ESF Agency for their review, cost estimation, and return to FEMA for final review and approval.

C.4.1.1 Initial FDA Internal Coordination (Field and Headquarters)

Initial FDA internal coordination (field and headquarters) including the following:

1. Activation of an ESF/RSF, where FDA is a support agency, may indicate that MAs may be sub-tasked to FDA. For incidents that may require FDA support to the States, OCM/OEO will inform the appropriate FDA Centers/Offices that activation has occurred and MA sub-tasks may be received.
2. If an FDA Incident Management Group (IMG) is established in the FDA Emergency Operations Center (EOC), MA sub-task reviews will be performed by the appropriate IMG member. If an IMG is not established, MA sub-task reviews will be performed by OCM/OEO. From this point forward in the appendix, the term “FDA EOC” refers to the IMG or OCM/OEO.
3. If an Incident Management Team (IMT) is established by an FDA Regional or District Office, MA sub-task reviews will be performed by the appropriate IMT member designated by the Incident Commander (IC). If an IMT is not established, MA sub-task reviews will be performed by the appropriate staff from the Regional or District Office.

C.4.2 Processing a Mission Assignment Sub-Task

FEMA may issue MAs to other Federal Agencies to (1) address a State’s request for Federal assistance to meet emergency needs or (2) support overall Federal operations pursuant to, or in anticipation of, a Stafford Act declaration.

C.4.2.1 FDA/FEMA/HHS Coordination

FDA/FEMA/HHS coordination will be as follows:

1. The FEMA JFO will develop an MA [see **Attachment C-3** (MA Form Based on Completed ARF Sample – FEMA Form 010-0-8)] based on the ARF. MA development will take place with input and review by the Regional Food and Drug Director (RFDD), District Director (DD), or designee from the relevant District, in consultation with the FDA EOC, and in coordination with the HHS Regional Emergency Coordinator (REC). The cost associated with the execution of the MA will be based on PSMA cost estimates or other cost information from the FDA Office of Regulatory Affairs (ORA) and/or relevant Centers.
2. FEMA will task HHS by sending the formal MA with the FEMA Integrated Financial Management Information System (IFMIS) stamp (certification of funds) to the HHS SOC (hhs.soc@hhs.gov).
3. The FDA EOC will alert the appropriate Centers\Offices that an MA sub-task is forthcoming.

4. Upon approval, HHS/ASPR A&F will send the MA to HHS EMG Operations for the final approval before sub-tasking FDA.
5. The HHS/ASPR A&F will send the signed sub-task to the FDA EOC obligating funds for FDA to respond to the State's request.
6. The FDA EOC will forward the sub-task to the ORA Office of Resource Management (ORM) and Office of Financial Management (OFM) for review and signature. Based on their review, ORA ORM/OFM will provide final review and signature and forward back to the FDA EOC.
7. The FDA EOC will scan the signed sub-task, enter it into the Emergency Operations Network – Incident Management System (EON-IMS) and send it back to the HHS SOC, with a copy to HHS/ASPR A&F.

C.4.2.2 FDA Internal Coordination

FDA internal coordination is as follows:

1. The FDA EOC notifies appropriate Regional and District staff and Centers/Offices of the sub-task approval.
2. Sub-tasks will be documented in the Incident Action Plan (IAP).
3. The FDA EOC transmits the sub-task funding requirements to the Office of the Commissioner (OC)/Office of Operations (OO)/Office of Finance, Budget, and Acquisition (OFBA)/Office of Financial Operations (OFO)/OFM/Division of Budget Execution and Control.
4. The Division of Budget Execution and Control informs the Office of Global Regulatory Operations and Policy (OGROP)/ORA/ORM/Division of Budget Formulation and Execution, which is responsible for issuing accounting data and providing funding to the District Office for response actions. OGROP/ORA/Office of Policy and Risk Management (OPRM)/Division of Planning, Evaluation, and Management may establish a Program Account Code (PAC) or refer to an existing one to provide for time reporting. Response personnel enter data (such as laboratory and investigation time expended) into the Field Accomplishments and Compliance Tracking System (FACTS) on an ongoing basis.
5. FDA field staff for the affected area notifies the FEMA JFO or Regional Office, the affected State(s), and others as appropriate of the receipt of a valid sub-tasking from HHS and corresponding authorization to take appropriate response actions.

C.4.2.3 MA Monitoring and Closeout

The MA monitoring and closeout process is as follows:

1. During operations under the sub-task, the FDA EOC will monitor the expenditure of funds in order to avoid potential over-spending. When the obligation level approaches 75 percent of authorized funds, the FDA EOC will notify HHS/ASPR A&F if any additional funding needs are anticipated. HHS/ASPR A&F will coordinate with FEMA to amend the MA as required. Justification for additional funding is required. The FDA EOC needs to be kept apprised of any changes in the scope of the sub-task.
2. When nearing completion of the mission, FDA field staff will discuss with the appropriate FEMA JFO ESF lead and State representatives any issues regarding the completion of the work and ensure the work has been completed in a satisfactory manner. Decisions regarding the official end date of the mission will be made during this communication.



3. Upon deactivation of the MA, FDA field staff must provide the FEMA MA Manager (with a courtesy copy to the Human Services Watch Officer) with a listing of any other ongoing sub-tasks and their status, Property Disposition Forms (if applicable), and financial and program points of contact (POCs).
4. Prior to demobilization, any deployed FDA personnel will notify their supervisor and the FDA EOC of travel arrangements.
5. The FDA EOC will compile and submit all data, costs, and supporting documentation as requested in the Stafford Act Mission Assignment Sub-Tasking Form [see example in **Attachment C-4**] to HHS/ASPR A&F.
6. HHS/ASPR A&F is responsible for submitting all close-out reports to the FEMA MA office for any additional eligible reimbursable costs incurred during the mission.



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Attachment C-1: FDA Pre-Scripted Mission Assignments

Requests for support from State and local agencies can be made directly to FDA or, in the case of a declaration of a major disaster or emergency, through FEMA. In order to assist States and local agencies with such requests, FDA has developed PSMA's under ESF #8, which can be used as examples to expedite the preparation and submission of such requests. Draft MA text is provided below.

Assistance Requested

HHS will provide food and product safety investigations to augment State and local staff in support of disaster operations in response to *[insert disaster name/#]*.

Statement of Work

At the direction of, and in coordination with FEMA, HHS will address immediate and short-term issues that impact whether food, drugs, biologics, and medical devices that have been directly affected by this incident are still appropriate for use. HHS will also assist in determining what steps, if any, may be employed to restore drugs, biologics, medical devices, and food to a condition whereby they would be fit for use. FDA investigators and consumer safety officers will assist State and local staff with the following services:

- Collect and analyze samples of foods, drugs, cosmetics, and/or medical devices for attributes, as necessary, to assist in providing assurance that commodities are fit for use.
- Conduct food safety inspections at retail food service establishments to ensure compliance with food safety standards, to include restaurants, school and hospital cafeterias, daycare center food service establishments, temporary shelters, and others.
- Conduct biologic, drug, and medical product safety inspections of pharmacies, hospitals, retail establishments, and other establishments that provide human and/or animal drugs, biologics, and medical devices to ensure these items have been stored under appropriate conditions and are fit for use.
- Conduct assessments for acceptable levels of radiation emission in facilities where diagnostic x-ray and mammography equipment are installed.
- Train disaster response personnel in food safety, preparation, handling, and storage.

Lease or Purchase of Accountable Property

None.

FEMA Logistical Support

- Teams may require some level of base operating support (e.g., food, shelter, laundry).
- MA task orders will be issued for individual personnel and/or teams as required by the incident and will specify times, location, and dates.
- HHS may sub-task other Federal Agencies for disaster medical support requirements as needed.

Type of Assistance

Direct Federal assistance.

Cost depends on which of the following resources are utilized. All teams will not necessarily be deployed:

- **FDA Retail Food Establishment Inspections.** FDA investigators (consumer safety officers) to augment State and local staff to perform inspections of establishments serving food at retail in *<location>* for conformance to appropriate food safety standards. Such establishments may include restaurants, school and hospital cafeterias, daycare center food service establishments, and temporary shelters, among others.
- **FDA Food, Cosmetic, and Medical Product Establishment Inspection.** FDA investigators (consumer safety officers) to augment State and local staff to conduct inspections of establishments that prepare, pack, and/or hold human and/or animal food, human and/or animal drugs, biologics, cosmetics, and/or medical devices to help ensure such commodities are safe, effective, and/or otherwise fit for use.
- **FDA Pharmacy Inspections.** FDA investigators (consumer safety officers) to augment State and local staff to perform inspections of pharmacies and other establishments offering human and/or animal drugs, biologics, and medical devices at retail to assist in ensuring such drugs, biologics, and medical devices have been stored under appropriate conditions and are fit for use.
- **FDA Sample Collections.** FDA investigators (consumer safety officers) to augment State and local staff to perform sample collections of human and/or animal foods, cosmetics, human and/or animal drugs, biologics, and medical devices for subsequent analyses.
- **FDA Analysts.** FDA analysts (including microbiologists, chemists, biologists, and other disciplines as appropriate) to augment State and local staff to analyze samples of foods, drugs, medical devices, and cosmetics to assist in providing assurance that these commodities are fit for use. Analyses may utilize FDA fixed site and/or mobile laboratories.
- **FDA Food Safety Training.** FDA investigators (consumer safety officers) or other FDA staff with food safety expertise to provide training in food safety preparation, handling, and storage to volunteers and/or other appropriate disaster response personnel.
- **FDA SMEs.** FDA SMEs to augment State and local staff to address issues that impact whether human and/or animal drugs, biologics, human and/or animal foods, and medical devices are appropriate for use and/or to provide guidance on what steps, if any, may be employed to restore human and/or animal drugs, biologics, human and/or animal foods, cosmetics, and medical devices to a condition whereby they would be fit for use.
- **FDA X-Ray Mammography Analysis.** FDA investigators (consumer safety officers) with expertise in this area to augment State and local staff to conduct assessments (field tests) of facilities where diagnostic x-ray and mammography equipment are installed, to help ensure the equipment is operating within acceptable radiation emission limits.



Attachment C-2:

ARF for FDA Retail Food Establishment Inspections Sample

Instructions on Completing the Action Request Form (ARF)

The State requesting assistance will need to complete Section I and Section II; most items are self-explanatory. For item II.1 (Description of Requested Assistance), the appropriate PSMA can form the basis for the text to be inserted. PSMA's serve only as a guide to expedite the process; the text can be modified as needed to reflect the mission, local conditions, and State requirements.

In addition, HHS requires a preliminary estimate of costs based upon the number of resources for the duration deployment. Use the following as a basis for an estimate:

1. **Deploy one investigator for 7 days: \$5,000**
(does not include standard pay; includes travel, per diem, and overtime)

Calculate:

Weeks x Personnel Deployed x 5,000 = Estimated Cost

Example:

2 weeks x 5 personnel x 5,000 = \$50,000

2. **Deploy one mobile laboratory for 7 days: \$40,000**

NOTE: The costs are only estimates that should be used for development of ARFs. These estimates may be adjusted by HHS/ASPR A&F or FEMA prior to issuance of the MA. If the funding amount on the sub-task is below the estimated cost provided by FDA, the Regional/District Office should notify the FDA EOC, who will discuss with HHS/ASPR A&F.



FDA Emergency Operations Plan



DEPARTMENT OF HOMELAND SECURITY
FEDERAL EMERGENCY MANAGEMENT AGENCY
ACTION REQUEST FORM (ARF)

See Reverse for Paperwork
Disclosure Notice

O.M.B No. 1660-0047
Expires March 31, 2014

I. REQUESTING ASSISTANCE (To be completed by Requestor)			
1. Requestor's Name (Please print) Kurt Donaldio		2. Title Program Manager	
3. Phone No. 606-555-8596		4. Requestor's Organization CMDOH	
5. Fax No.		6. E-Mail Address kurt.donaldio@doh.state.cm	
II. REQUESTING ASSISTANCE (To be completed by Requestor)			
1. Description of Requested Assistance: FDA investigators (consumer safety officers) to augment State and local staff to perform inspections of establishments serving food at retail establishments for conformance to appropriate food safety standards. Such establishments may include restaurants, school and hospital cafeterias, daycare center food service establishments, and temporary shelters, among others.			
2. Quantity	3. Priority <input checked="" type="checkbox"/> Lifesaving <input type="checkbox"/> Life Sustaining <input type="checkbox"/> Normal	4. Date and Time Needed	
5. Delivery Site Location		6. Site Point of Contact (POC)	
		7. 24 Hour Phone No.	8. Fax No.
9. State Approving Official Signature		10. Date and Time	
III. SOURCING THE REQUEST - REVIEW/COORDINATION (Operations Section Only)			
1. <input checked="" type="checkbox"/> OPS Review by: s/MJK <input type="checkbox"/> LOG Review by: <input type="checkbox"/> Other Coordination: <input type="checkbox"/> Other Coordination: <input type="checkbox"/> Other Coordination:		2. Source: <input type="checkbox"/> Donations <input type="checkbox"/> Other (Explain) <input type="checkbox"/> Requisitions <input type="checkbox"/> Procurement <input type="checkbox"/> Interagency Agreement <input type="checkbox"/> Mission Assignment	
3. Assigned to: ESF/OFA: HHS Other: Date/Time:		4. Immediate Action Required <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
IV. STATEMENT OF WORK (Operations Section Only)			
1. OFA Action Officer		2. 24 Hour Phone No.	3. Fax No.
4. FEMA Project Manager		5. 24 Hour Phone No.	6. Fax No.
7. Statement of Work		<input type="checkbox"/> See Attached	
8. Estimated Completion Date		9. Estimated Cost	
V. ACTION TAKEN (Operations Section Only)			
<input checked="" type="checkbox"/> Accepted <input type="checkbox"/> Rejected <input type="checkbox"/> Requestor Notified			
Reason / Disposition			
TRACKING INFORMATION (FEMA Use Only)			
ECAPS/NEMIS Task ID:		Action Request No.	Program Code/Event No.
Received by (Name and Organization)		State	Date/Time Received
<input type="checkbox"/> Originated as verbal			

FEMA Form 010-0-7, (3/2011)

PREVIOUSLY FF 90-136



Attachment C-3: MA Form Based On Completed ARF Sample

DEPARTMENT OF HOMELAND SECURITY FEDERAL EMERGENCY MANAGEMENT AGENCY MISSION ASSIGNMENT (MA)		See Reverse for Paperwork Burden Disclosure Notice	O.M.B. NO. 1660-0047 Expires March 31, 2014
I. TRACKING INFORMATION (FEMA Use Only)			
State CM (State of Columbia) Incident: 2012102505-Hurricane Zulu		NEMIS Number 1509-150671	
Program Code/Event Number 4086DR-CM: HURRICANE ZULU		Date/Time Received 12/04/2012 23:06	
II. ASSISTANCE REQUIRED <input type="checkbox"/> See Attached			
Assistance Requested HHS will provide food and product safety investigators to augment state, tribal and local staff in support of disaster operations in response to Hurricane Zulu in the State of Columbia			
Delivery Location Various locations throughout Columbia		Internal Control Number ARF #198-46	Date/Time Required 12/05/2012
Initiator/Requestor Name Kurt Donaldio	24 Hour Phone Number (609) 555-8596	Email Address kurt.donaldio@doh.state.cm	Date 12/04/2012
Site POC Name JAMES ALFRED	24 Hour Phone Number (816) 555-7010	Email Address jim.alfred@fema.dhs.gov	Date 12/04/2012
* State Approving Official (Required for DFA and TA)			Date
III. INITIAL FEDERAL COORDINATION (Operations Section)			
Action to:	<input checked="" type="checkbox"/> ESF #: 8 <input type="checkbox"/> Other:	Date/Time 12/04/2012 22:52	Priority <input type="checkbox"/> 1. Lifesaving <input checked="" type="checkbox"/> 3. High <input type="checkbox"/> 2. Life sustaining <input type="checkbox"/> 4. Medium
IV. DESCRIPTION (Assigned Agency Action Officer) <input checked="" type="checkbox"/> See Attached			
Statement of Work At the direction of, and in coordination with FEMA, HHS will provide food and product safety investigators to augment state and local staff to perform inspections of establishments serving food at retail establishments for conformance to appropriate food safety standards. Such establishments may include restaurants, school and hospital cafeterias, day care center food service establishments, temporary shelters, among others. Your agency must validate the unliquidated MA balance at least annually as stipulated by FEMA to maintain reimbursable authority. Accrual data must also be provided to FEMA no later than the third business day after fiscal quarter end close. Information can be submitted FEMA-Disaster-MA-ULO@DHS.gov			
Assigned Agency HHS (DEPT OF HEALTH & HUMAN SVC)		Projected Start Date 12/06/2012	Projected End Date 1/31/2013
<input checked="" type="checkbox"/> New or <input type="checkbox"/> Amendment to MA #:		Total Cost Estimate \$385,000.00	
ESF/OFA Action Officer RONALD LENZI		Phone No. (303) 555-0400	Email ronald.lenzi@hhs.gov
V. COORDINATION (FEMA Use Only)			
Type of MA:	<input checked="" type="checkbox"/> Direct Federal Assistance State Cost Share (0%, 10%, 25%)	<input type="checkbox"/> Technical Assistance State Share (0%)	<input type="checkbox"/> Federal Operations Support State Share (0%)
State Cost Share Percent 25.0 %		State Cost Share Amount: \$ 96,250.00	
Fund Citation: 2013-06-4086DR-9J24-XXXX-2608-D		Appropriation code: 70X0702	
Mission Assignment Manager (Preparer) MINDY McDONALD		Date 12/05/2012	
** FEMA Project Manager/Branch Director (Program Approval) JAMES DONLEE		Date 12/05/2012	
** Comptroller/Funds Control (Funds Review) KENNEDY JEFFERS		Date 12/05/2012	
VI. APPROVAL			
* State Approving Official (required for DFA and TA):			Date
** Federal Approving Official (required for all): JACK GRAHAM			Date 12/05/2012
VII. OBLIGATION (FEMA Use Only)			
Mission Assignment Number 4086DR-CM-HHS-05	Amount This Action \$ 385,000.00	Date/Time Obligated	12/06/2012
Amendment Number 00	Cumulative Amount \$ 385,000.00	Initials/FMI	
* Signature required for Direct Federal Assistance and Technical Assistance MAs. ** Signature required for all MAs.			

FEMA Form 010-0-8, (3/2011)

PREVIOUSLY FF 90-129



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Attachment C-4: Stafford Act Mission Sub-Tasking Based on MA Form Sample

Stafford Act Mission Assignment Sub-Tasking Form		
Mission Assigned Primary Agency:	U.S. Department of Health and Human Services (HHS)	
Sub-Tasked Agency:	U.S. Food and Drug Administration (FDA)	
Tasking Statement/Statement of Work:	Provide food and product safety investigators to augment State, tribal, and local staff in support of disaster operations in response to Hurricane Zulu and in the State of Columbia. This tasking covers incremental salaries and travel expenses starting on December 6, 2012.	
Project Completion Date:	January 31, 2013 (may be extended by email from Mr. David Dolinsky)	
Authorized Funding:	\$380,000	
Statutory Authority:	Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, as amended, 42 U.S.C. 5121-5201	
Accounting Information:	FDA shall bill and provide supporting documentation to HHS/ASPR using the following information:	
	To: FDA	From: HHS/ASPR
Agency Location Code (ALC):	75060099	75030030
Appropriation Number:		47-31-1004
Mission Assignment Number:	4086DR-CM-HHS05	4086DR-CM-HHS05
CAN / Account Number:		1996389
Object Class:	Multiple	25308
Amount This Action:	\$380,000	\$380,000
DUNS Number:	927645532	803192033
Document Number:		
Employer Identification Number (EIN):	53-0196965	26-1864515
<p>HHS/ASPR, the primary agency, is responsible for monitoring the work progress of a sub-tasked support agency and approving the request for reimbursement submitted by the support agency. Any costs and supporting documentation must be provided to the HHS/ASPR POC prior to submitting and Intra-Governmental Payment and Collection (IPAC). This sub-task will be automatically closed and deobligated 60 days after the project completion date if costs are not presented. As such, all documentation supporting requests for reimbursement shall be submitted to:</p> <p>David A. Dolinsky, CPA Deputy Director for Administration and Finance Operations ASPR/Office of Financial Planning and Analysis U.S. Department of Health and Human Services 200 Independence Avenue, SW, Room 638G Washington, DC 20201 202-205-0499 (Office) david.dolinsky@hhs.gov</p>		

**Accounting Information:** *(continued)*

Reimbursement and billing will be accomplished through the IPAC System.

Program Support Center (PSC), Division of Financial Operations (DFO)
Room 16-30
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

IPAC will make disbursements/payments.

Document number, ALC, accounting codes, and dollar amounts must be referenced.

Authorizing Officials**For FDA:**

Signed: _____ Date: _____
Name/Title

For HHS/ASPR:

Signed: _____ Date: _____
David A. Dolinsky
Deputy Director for Administration and Finance
Operations/A+F Section Chief

Funds Certification (ASPR):

Signed: _____ Date: _____
Name/Title

Appendix D: Characteristics of Potential Foodborne Agents¹

Agent	Incubation Period ^{2,3}	Availability	Minimum Infectious Dose, Secondary Transmission	Clinical Syndrome	Case Fatality	Other Characteristics of Microbe or Illness
Botulinum toxin	Generally between 12 to 72 hours Dependent on the toxin dose, the incubation period varies from 2 hours to 10 days	Organism ubiquitous in environment; cultures need anaerobic conditions	LD ₅₀ = 0.001 µg/kg The best estimate of median oral lethal dose for people is 0.2 to 2.0 micrograms	Descending paralysis, respiratory compromise	5% (treated)	95% of patients need hospitalization; 60% of patients need intubation
<i>Salmonella</i> serotypes (excluding <i>Salmonella typhi</i>)	Can be as short as 6 hours, but is generally 12 to 36 hours	Clinical and research laboratories, culture collections, poultry, environmental sources	10 ³ organisms; limited secondary transmission	Acute diarrheal illness, 1 to 3% chronic sequelae	>1%	Organism hardy; lengthened survival in the environment
<i>Salmonella typhi</i>	24 to 72 hours	Clinical and research laboratories	10 ⁵ organisms; secondary transmission possible Reports exist of illness associated with ingested doses in the range of 100s to 100,000 for <i>S. typhi</i>	Acute febrile illness, protracted recovery, 10% relapse, 1% intestinal rupture	10% untreated, 1% treated	Clinical syndrome unfamiliar in the United States; long incubation period (1 to 3 weeks); produces asymptomatic carrier rate in 3% of cases
<i>Shigella</i> spp.	24 to 48 hours	Clinical and research laboratories	10 ² organisms; secondary transmission possible	Acute diarrhea, often bloody	For most common species in the United States, <1%	

¹ Sobel, J., A.S. Khan, and D.L. Swerdlow. "Threat of a Biological Terrorist Attack on the U.S. Food Supply: The CDC Perspective." *The Lancet*, Vol. 359(9309), 874–880, March 9, 2002.

² "Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians and Other Health Care Professionals." *CDC Morbidity and Mortality Weekly Report (MMWR)*, Vol. 53, No. RR-4, April 16, 2004.

³ *Bad Bug Book – Foodborne Pathogenic Microorganisms and Natural Toxins Handbook* (Second Edition), FDA Center for Food Safety and Applied Nutrition (CFSAN), 2012.



Agent	Incubation Period ^{2,3}	Availability	Minimum Infectious Dose, Secondary Transmission	Clinical Syndrome	Case Fatality	Other Characteristics of Microbe or Illness
<i>Shigella dysenteriae</i> type 1	12 to 50 hours	Clinical and research laboratories	10 to 100 organisms; secondary transmission possible	Dysentery, seizures	Up to 20% (treated)	Causes dysentery, toxic megacolon, hemolytic uremic syndrome (HUS), convulsions in children
<i>Escherichia coli</i> O157:H7	24 to 72 hours, but may be as long as 10 days	Clinical and research laboratories, bovine sources, farms	>50 organisms; secondary transmission possible The infectious dose ranges between 1 and 100 cells	Acute bloody diarrhea, 5% HUS, longer term complications	1%	Long-term sequelae: hypertension, stroke, renal insufficiency/failure neurological complications
<i>Vibrio cholerae</i>	24 to 72 hours	Clinical and research laboratories	10 ⁶ organisms; secondary transmission possible Feeding studies using healthy humans indicated that 1x10 ⁶ organisms must be ingested to cause illness. Outbreak investigations of natural cholera suggest that, if ingested with water, the infectious dose is 10 ³ to 10 ⁶ organisms; if ingested with food, the infectious dose is 10 ² to 10 ⁴ organisms.	Acute life-threatening dehydrating diarrhea	Up to 50% untreated; 1% treated	Historically, causes massive waterborne epidemics in areas with poor sanitation

Appendix E: Chemical Agents – Background Information¹

Items in this section are as follows:

- General Information
- Classes of Chemical Warfare Agents
- Nerve Agent Exposure Versus Nerve Agent Intoxication
- Chemical Agent Characteristics
- List of Additional Chemical Agents

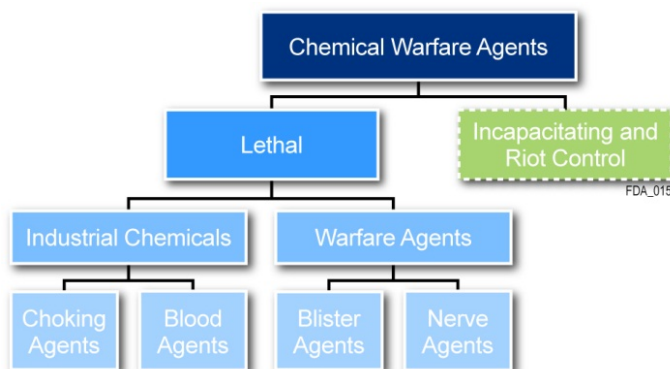
Additional information on chemical agents may be found at <http://emergency.cdc.gov/chemical/>.

E.1 GENERAL INFORMATION

Chemical agents are:

- Generally liquid (when containerized).
- Normally disseminated as aerosol or gas.
- Present a respiratory, dermal, ocular, and mucus membrane hazard.
- May be detectable by smell or other senses, but not consistent for all agents.
- Dispersal or lack thereof by weather conditions impacts hazard of agent.

E.2 CLASSES OF CHEMICAL WARFARE AGENTS



Lethal

- **Industrial Chemicals**
 - **Choking Agents (Pulmonary Agents).** Choking agents primarily attack lung tissue, causing pulmonary edema. However, there may also be mild irritation of the eyes and upper respiratory tract.
 - **Blood Agents (Cyanides).** Blood agents enter the body following ingestion, skin contact, or inhalation. Once in the body, blood agents inactivate a critical enzyme (cytochrome oxidase); this prevents the cell from using oxygen. Symptoms of blood agent poisoning include respiratory changes, convulsions, and death.

¹ Access additional training in this area via the online courses offered by ORA University at <http://intranet.ora.fda.gov/dhrd/default.htm>.

- **Warfare Agents**

- **Blister Agents (Vesicants).** Blister agents include the mustards, arsenicals (primarily Lewisite), and phosgene oxime. They cause pain and tissue damage. Mustards can have delayed effects (hours), but Lewisite and phosgene oxime cause immediate effects. Vesicants cause either fluid-filled blisters or red, elevated skin lesions (phosgene oxime).
- **Nerve Agents.** Nerve agents cause the greatest concern because of their toxicity, rate of action, and ability to enter the body by multiple routes of entry. Nerve agents are extremely fast acting and classically categorized as colorless and odorless. The symptoms of nerve agents include dimness of vision, runny nose, drooling, difficulty breathing/tightness of chest, nausea, vomiting and diarrhea, muscle jerking or twitching, involuntary urination, defecation, coma, and death.

Incapacitating and Riot Control

Incapacitating and riot control agents are not primary terrorist threats due to their relatively short duration of effects and minimal toxicity.

E.3 NERVE AGENT EXPOSURE VERSUS NERVE AGENT INTOXICATION

“SLUDGE,” bracketed in the box below, is an acronym often used by medical personnel for identifying the symptoms of organophosphate poisoning.

		Vapor Exposure	Liquid Exposure
Mild	P Pinpointing pupils	X	
	S Salivation	X	
	L Lacrimation (tearing)	X	
Severe	U Urination	X	X
	D Defecation	X	X
	G Gastrointestinal; pain and gas	X	X
	E Emesis (vomiting)	X	X
	M Muscle twitching	X	X
	C Convulsions, coma	X	X

FDA_0716a

E.4 CHEMICAL AGENT CHARACTERISTICS

Type of Agent	Effects	Onset	First Aid	Skin Decontamination	Detection
Pulmonary TIC: CG (PFIB, HC)	Dyspnea, coughing	Hours	None	None usually needed	None
Cyanide: AC, CK	Loss of consciousness, convulsions, apnea	Seconds	None (nitrite and thiosulfate)	None usually needed	M256A1
Vesicants: H, HD, L	Erythema, blisters; irritation of eyes; cough; dyspnea Vapor: miosis, rhinorrhea, dyspnea	Hours (immediate pain after L) Vapor: seconds	None	M291, M258A1, soap and water, 0.5% bleach	M256A1, M8 and M9 papers, CAM, ACADA, FOX, M90
Nerve: GA, GB, GD, GF, VX	Vapor: miosis, rhinorrhea, dyspnea Liquid: sweating, vomiting Both: convulsions, apnea	Vapor: seconds Liquid: minutes to hours	MARK I (1 to 3), Diazepam Antidote Treatment: Nerve Agent Autoinjector	M291, M258A1, soap and water, 0.5% bleach	M8A1 alarm, M256A1, M8 and M9 papers, CAM, M22 ACADA
Incapacitating: BZ, Agent 15	Mydriasis, increased body temperature; dry mouth and skin; confusion, visual hallucinations	Minutes to hours	Remove from harming themselves or others	Remove outer clothing; water, or soap and water	None
Riot Control: CS, CN	Burning, stinging of eyes, nose, airways, skin	Seconds	None	Water	None

Adapted from the U.S. Army Medical Research Institute of Chemical Defense's (USAMRICD) *Medical Management of Chemical Casualties Handbook*, Fourth Edition, Appendix F, February 2007.

The *Medical Management of Chemical Casualties Handbook* states, "The [above] table is intended to serve as a reminder of the agents, their effects, first-aid measures, detection, and skin decontamination. It is in no way complete, nor is it intended to be complete." Consult the appropriate Center SMEs for more detailed information.

E.5 LIST OF ADDITIONAL CHEMICAL AGENTS

Available at www.bt.cdc.gov/agent/agentlistchem.asp with links for agent description.

Chemical Agents	
Abrin	Methyl Isocyanate
Adamsite (Diphenylaminechloroarsine or DM)	Mustard Gas (H) (Sulfur Mustard)
Ammonia	Mustard/Lewisite (HL)
Arsenic	Mustard/T
Arsine (SA)	Nicotine
Barium	Nitrogen Mustard (HN-1, HN-2, HN-3)
Benzene	Opioids
Brevetoxin	Osmium Tetroxide
Bromine (CA)	Paraquat
Bromobenzylcyanide (CA)	Phosgene (CG)
BZ (3-Quinuclidinyl Benzilate)	Phosgene Oxime (CX)
Carbon Monoxide	Phosphine
Chlorine (CL)	Phosphorus, elemental, white or yellow
Chloroacetophenone (CN)	Potassium Cyanide (KCN)
Chlorobenzylidenemalononitrile (CS)	Ricin *
Chloropicrin (PS)	Sarin (GB)
Chromium	Saxitoxin
Colchicine	Selenium
Cyanide	Sesqui Mustard
Cyanogen Chloride (CK)	Sodium Azide
Dibenzoxazepine (CR)	Sodium Cyanide (NaCN)
Diphosgene (DP)	Sodium Monofluoroacetate (compound 1080)
Distilled Mustard (HD)	Soman (GD)
Ethylene glycol	Stibine
Fentanyl and Other Opioids	Strychnine
Hydrazine	Sulfur Mustard (H) (Mustard Gas)
Hydrofluoric Acid (Hydrogen Fluoride)	Sulfur Fluoride
Hydrogen Chloride	Super Warfarin (Long-Acting Anticoagulant)
Hydrogen Cyanide (AC)	Tabun (GA)
Hydrogen Fluoride (Hydrofluoric Acid)	Tetrodotoxin
Lewisite (L, L-1, L-2, L-3)	Thallium
LSD (Lysergic Acid Diethylamide)	Trichothecene
Mercury	VX
Methyl Bromide	White Phosphorus

*May also be considered a biological agent.

For more information on chemical emergencies, including specific chemical agents, information for the public and information for first responders, refer to CDC's Emergency Preparedness and Response website at www.bt.cdc.gov/chemical/.



For response information for thousands of hazardous materials, including fire and explosion hazards, health hazards, firefighting techniques, cleanup procedures, protective clothing, and chemical properties, refer to www.cameochemicals.noaa.gov/search/simple.



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Appendix F: Biological Agents – Background Information¹

Items in this section are as follows:

- General Information
- Classes of Biological Warfare Agents
- Epidemiologic Clues That May Signal a Covert Bioterrorism Attack
- Bioterrorism Agents/Diseases By Category

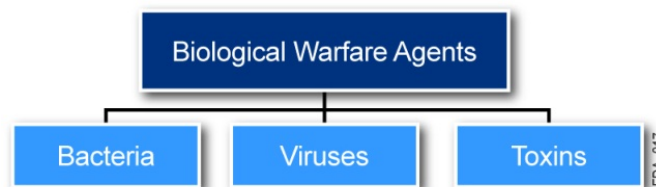
Additional information on bioterrorism may be found at www.bt.cdc.gov/bioterrorism/.

F.1 GENERAL INFORMATION

Biological agents:

- Produce delayed effects.
- Do not penetrate unbroken skin.
- Do not evaporate.
- Undetectable by senses.
- Difficult to detect in the field.
- Have a range of effects.
- Usually obtained from nature.
- Can now be produced synthetically starting with coding sequence.
- May be engineered for increased virulence.
- Have multiple routes of entry.
- Potentially destroyed by environment.
- Some are contagious.
- Virtually impossible to limit spread or deliberate delivery.
- Environmental detection systems (e.g., BioWatch) for some are now operational.
- Countermeasures are available for some agents.
- Quarantine strategies may be implemented in an effort to control a biological contagion.

F.2 CLASSES OF BIOLOGICAL WARFARE AGENTS



Bacteria. Bacteria are living unicellular organisms and are predominantly self-sufficient (with the exception of several intracellular species that require a host cell to survive). Bacteria require varying conditions of light, moisture, pH, and temperature to survive. Bacteria cause disease in humans by

¹ Access additional training in this area via the online courses offered by ORA University at <http://intranet.ora.fda.gov/dhrd/default.htm>.

invading host tissues, by producing toxins, or both. The diseases they produce often respond to specific antibiotic therapies.

Viruses. Viruses need a “host” cell to live and multiply. However, viruses are technically considered living organisms because they contain genetic material. Although environmental detection units utilizing Polymerase Chain Reaction (PCR) technology can detect viruses, they generally would not be able to assess whether or not the virus is viable.

Toxins. Toxins are harmful substances produced by bacteria, plants, and animals. These range from animal venoms (e.g., snake or spider bite), to plant toxins (e.g., ricin), to bacteria toxins (e.g., botulinum toxin). Since they are biochemical moieties (e.g., proteins), they do not replicate and (unlike chemical agents) are nonvolatile and unlikely to cause secondary exposures.

F.3 EPIDEMIOLOGIC CLUES THAT MAY SIGNAL A COVERT BIOTERRORISM ATTACK

Adapted below is a CDC list of epidemiologic clues that may signal a biological incident. In addition, FDA may receive information through its adverse event reporting systems, which indicate a possible biological agent contamination. This list provides the opportunity to recognize and respond to the early clues, important for minimizing the harmful impacts of a biological incident.

Epidemiologic clues are as follows:

- A preliminary positive signal from BioWatch systems.
- A signal from the BioSense system.
- Intelligence.
- Containers of powders or liquids that are in inappropriate places.
- Large numbers of ill persons with similar disease or syndrome.
- Large numbers of unexplained disease, syndrome, or deaths.
- Unusual illness in a population.
- Higher morbidity and mortality than expected with a common disease or syndrome.
- Failure of a common disease to respond to usual therapy.
- Single case of disease caused by an uncommon agent.
- Multiple unusual or unexplained disease entities coexisting in the same patient without other explanation.
- Disease with an unusual geographic or seasonal distribution.
- Multiple atypical presentations of disease agents.
- Similar genetic type among agents isolated from temporally or spatially distinct sources.
- Unusual, atypical, genetically engineered, or antiquated strain of agent.
- Endemic disease with unexplained increase in incidence.
- Simultaneous clusters of similar illness in noncontiguous areas, domestic or foreign.
- Atypical aerosol, food, or water transmission.
- Ill people presenting near the same time.
- Deaths or illness among animals that precedes or accompanies illness or death in humans.
- No illness in people not exposed to common ventilation systems, but illness among those people in proximity to the systems.

F.4 BIOTERRORISM AGENTS/DISEASES BY CATEGORY

This table was created from information from the CDC Bioterrorism Agents/Diseases by category list (available at www.bt.cdc.gov/agent/agentlist-category.asp).

Biological Diseases/Agents	
Category A	
Definition: The U.S. public health system and primary healthcare providers must be prepared to address various biological agents, including pathogens that are rarely seen in the United States. High-priority agents include organisms that pose a risk to national security because they: <ul style="list-style-type: none"> Can be easily disseminated or transmitted from person to person; Result in high mortality rates and have the potential for major public health impact; Might cause public panic and social disruption; and Require special action for public health preparedness. 	
Category A Agents/Diseases	
Anthrax (<i>Bacillus anthracis</i>)	
Botulism (<i>Clostridium botulinum</i> toxin)	
Plague (<i>Yersinia pestis</i>)	
Smallpox (variola major)	
Tularemia (<i>Francisella tularensis</i>)	
Viral hemorrhagic fevers (filoviruses [e.g., Ebola, Marburg] and arenaviruses [e.g., Lassa, Machupo])	
Category B	
Definition: Second highest priority agents include those that: <ul style="list-style-type: none"> Are moderately easy to disseminate; Result in moderate morbidity rates and low mortality rates; and Require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance. 	
Category B Agents/Diseases	
Brucellosis (<i>Brucella</i> species)	
Epsilon toxin of <i>Clostridium perfringens</i>	
Food safety threats (e.g., <i>Salmonella</i> species, <i>Escherichia coli</i> O157:H7, <i>Shigella</i>)	
Glanders (<i>Burkholderia mallei</i>)	
Meliodiosis (<i>Burkholderia pseudomallei</i>)	
Psittacosis (<i>Chlamydia psittaci</i>)	
Q fever (<i>Coxiella burnetii</i>)	
Ricin toxin from <i>Ricinus communis</i> (castor beans)	
Staphylococcal enterotoxin B	
Typhus fever (<i>Rickettsia prowazekii</i>)	
Viral encephalitis (alphaviruses [e.g., Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis])	
Water safety threats (e.g., <i>Vibrio cholerae</i> , <i>Cryptosporidium parvum</i>)	
Category C	
Definition: Third highest priority agents include emerging pathogens that could be engineered for mass dissemination in the future because of: <ul style="list-style-type: none"> Availability; Ease of production and dissemination; and Potential for high morbidity and mortality rates and major health impact. 	
Category C Agents	
<ul style="list-style-type: none"> Emerging infectious disease threats such as Nipah virus and hantavirus 	

For more information on specific biological agents/diseases, including agent lists, factsheets, questions and answers, references, treatment, laboratory information, and more, refer to the CDC's Emergency Preparedness and Response website at www.bt.cdc.gov/agent/agentlist.asp.



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Appendix G: Oversight of Select Agents and Toxins by HHS/CDC and USDA/Animal and Plant Health Inspection Service

(7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73)

G.1 HHS SELECT AGENTS AND TOXINS

- Abrin
- Botulinum neurotoxins
- Botulinum neurotoxin producing species of *Clostridium*
- Cercopithecine herpes virus 1 (Herpes B virus)
- *Clostridium perfringens* (Epsilon toxin)
- *Coccidioides posadasii*/*Coccidioides immitis*
- Conotoxins
- *Coxiella burnetii* (Q fever)
- Crimean-Congo haemorrhagic fever virus
- Diacetoxyscirpenol
- Eastern Equine Encephalitis virus
- Ebola virus
- *Francisella tularensis* (tularemia)
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
- Ricin
- *Rickettsia prowazekii* (typhus fever)
- *Rickettsia rickettsii*
- Saxitoxin
- Shiga-like ribosome inactivating proteins
- Shigatoxin Lumpy skin disease virus
- South American Haemorrhagic Fever viruses
 - Flexal
 - Guanarito
 - Junin
 - Machupo
 - Sabia
- Staphylococcal enterotoxins
- T-2 toxin
- Tetrodotoxin
- Tick-borne encephalitis complex (flavi) viruses
 - Central European Tick-borne encephalitis
 - Far Eastern Tick-borne encephalitis
 - Kyasanur Forest disease
 - Omsk Hemorrhagic Fever
 - Russian Spring and Summer encephalitis
- Variola major virus (smallpox virus)
- Variola minor virus (Alastrim)
- *Yersinia pestis* (plague)

G.2 OVERLAP SELECT AGENTS AND TOXINS

- *Bacillus anthracis* (anthrax)
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei* (formerly *Pseudomonas mallei*)
- *Burkholderia pseudomallei* (formerly *Pseudomonas*)

- Hendra virus
- Nipah virus
- Rift Valley fever virus
- Venezuelan Equine Encephalitis virus

G.3 USDA SELECT AGENTS AND TOXINS

- African horse sickness virus
- African swine fever virus
- Akabane virus
- Avian influenza virus (highly pathogenic)
- Bluetongue virus (exotic)
- Bovine spongiform encephalopathy agent
- Camel pox virus
- Classical swine fever virus
- *Ehrlichia ruminantium* (Heartwater)
- Foot-and-mouth disease virus
- Goat pox virus
- Japanese encephalitis virus
- Lumpy skin disease virus
- Malignant catarrhal fever virus
- Menangle virus
- *Mycoplasma capricolum* subspecies *capripneumoniae* (contagious caprine pleuropneumonia)
- *Mycoplasma mycoides* subspecies *mycoides* small colony (*MmmSC*) (contagious bovine pleuropneumonia)
- Peste des petits ruminants virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3
- Virulent Newcastle disease virus¹

¹ A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

G.4 USDA PLANT PROTECTION AND QUARANTINE SELECT AGENTS AND TOXINS

- *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)
- *Phoma glycinicola* (formerly *Pyrenochaeta glycines*)
- *Ralstonia solanacearum* race 3, biovar 2
- *Rathayibacter toxicus*
- *Sclerophthora rayssiae* var *zeae*
- *Synchytrium endobioticum*
- *Xanthomonas oryzae*
- *Xylella fastidiosa* (citrus variegated chlorosis strain)

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Appendix H: Domestic and International Traceback/Traceforward

H.1 DOMESTIC

When there is an FDA-regulated product potentially affected by an emergency, it is necessary to determine all distribution of the affected product. After appropriate consultation with others (State and local officials, Centers, and CDC), the FDA EOC, in coordination with the Office of Regional Operations (ORO), initiates a traceback/traceforward investigation.¹ The FDA EOC coordinates the tracing (forward and backward) of the distribution of any potentially contaminated FDA-regulated products and initiates seizures or recalls as appropriate. CDC and local or State agencies may provide assistance on the traceback/traceforward.

H.2 INTERNATIONAL

If FDA determines international distribution of the product occurred, the Office of International Programs (OIP) notifies foreign governments of the situation as appropriate. OIP is also FDA's lead office for communicating with various international stakeholders, including the U.S. Department of State (DOS), foreign and U.S. embassies, foreign governments (including counterpart foreign agencies), and international organizations. When FDA learns of suspect or actual incidents involving FDA-regulated products received from or sent to foreign countries, the FDA EOC promptly notifies the Deputy Commissioner for International Programs and the Assistant Director for Communications in OIP, who then coordinates with recall personnel and/or other appropriate staff for the notification and exchange of information with the affected countries.

In addition, OIP coordinates with the FDA EOC to provide timely notification with the appropriate degree of urgency to the following offices as necessary and appropriate:

- FDA Center international offices or liaisons
- Embassies of the country or countries involved
- HHS Office of Global Health Affairs
- Desk officers at DOS
- Other relevant U.S. agency international components
- Appropriate international organizations

Epidemiological traceback data provides the basis for enforcement strategies. At the border, this includes procedures to facilitate movement of similar products that are in compliance with the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act) (as mandated in Section 302 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Bioterrorism Act]) or otherwise not considered a serious threat to public health and safety. Epidemiological traceback data provides intelligence that allows FDA to identify historical shipments through the same or similar streams of commerce of implicated products for appropriate follow-up. Follow-up activities include visiting importers and consignees of previous shipments to identify disposition of imported goods and identifying individuals and firms responsible for the sale, purchase, and receipt of implicated products.

¹ For more information on how the FDA conducts traceback investigations, refer to www.fda.gov/ICECI/Inspections/InspectionGuides/ucm075005.htm and the FDA's "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations" (June 2006).



The agency will use the Operational and Administrative System for Input Support or the Mission Activity Reporting and Compliance System and may work with the U.S. Customs and Border Protection (CBP), located at the Commercial Trade Analytical Center, to analyze entry data in order to support decisions for dispatching human resources through assignments or other methods established for rapid response to support operations. The Director of the Division of Import Operations and Policy (DIOP) will advise CBP of the situation and the information needed to use CBP's Automated Targeting System (ATS) to detect and detain future shipments of potentially tainted products before their introduction into U.S. commerce.

Appendix I: Memorandum of Understanding

A memorandum of understanding (MOU) is a critical component of any formal arrangement of cooperation between two or more entities. An MOU usually describes, in broad general terms, an area of mutual interest or concern that two or more agencies or organizations may cooperatively address. MOUs generally do not include specific information regarding detailed scope of work or exchange of funds or human resources. Below is a table of the current, finalized MOU that FDA has with other organizations.

A complete listing of **MOUs or other written cooperative arrangements** with States, other Federal Agencies and foreign government counterparts, and the World Health Organization (WHO) can be found at www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/default.htm.

Understanding or Agreement	Purpose	Parties and/or Participants	Link	Notes/Dates (Effective/Expiration)
225-09-0002	Exchange of information and coordination of actions	FDA and CDC	www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm212905.htm	02/25/2009 02/25/2014
225-12-0007	Exchange of information	FDA and USDA FFAS/ FNCS/FS/MRP/ REE*	www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm294512.htm	01/19/2012 Indefinite
225-72-2009	Cooperation and information sharing	FDA and USDA Agricultural Marketing Service (AMS)	www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115864.htm	03/04/2011 Indefinite
225-11-0002	Establishing terms of collaboration in areas of common interest and shared responsibility	FDA and USDA REE	www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmou/domesticmou/ucm261929.htm	07/01/2011 07/01/2016
225-11-0019	Exchange of information	FDA and USDA AMS/Food Service Agency (FSA)/ Food and Nutrition Service (FNS)	www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm293689.htm	09/29/2011 09/11/2016
N/A	Sharing and exchange of Information	FDA and Health Products and Food Branch (HPFB), Health Canada of Canada	www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm197838.htm	04/16/2008 11/18/2013
225-96-4001	Trilateral: cooperation in scientific and regulatory fields of health	FDA; Health Protection Branch (HPB), Health Canada of Canada; and Subsecretaría de Regulación y Fomento Sanitario of the Secretaría de Salud (SSA) of the United Mexican States	www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm107612.htm	10/30/1995 Indefinite

*USDA Farm and Foreign Agricultural Services (FFAS)/Food, Nutrition, and Consumer Services (FNCS)/Food Safety (FS)/Marketing and Regulatory Programs (MRP)/Research, Education, and Economics (REE)



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Appendix J: Forms and Templates

Listed below are some common forms and templates to be used by FDA personnel during the course of an incident. Hyperlinks attached to each title link directly to the appropriate form/template included within this appendix. Electronic copies can be found on the EON-IMS.

Title	Page #
Incident Briefing (ICS 201) , Adapated for FDA	App J-3
Incident Objectives (ICS 202) , Adapated for FDA	App J-7
Organization Assignment List (ICS 203) , Adapted for FDA	App J-9
Assignment List (ICS 204) , Adapated for FDA	App J-11
Incident Communications Plan (ICS 205) , Adapated for FDA	App J-13
Medical Plan (ICS 206) , Adapted for FDA	App J-15
Safety Message/Plan (ICS 208)	App J-17
Incident Check-In List (ICS 211) , Adapted for FDA	App J-19
Resource Request (ICS 213 RR) , Adapted for FDA	App J-21
Activity Log (ICS 214)	App J-23
Operational Planning Worksheet (ICS 215)	App J-25
Incident Action Plan Safety Analysis (ICS 215A)	App J-27
Demobilization Check-Out (ICS 221) , Adapted for FDA	App J-29
Situation Report	App J-31



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Appendix J: Forms and Templates

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Updated by FDA 2/2011



1. Incident Name:		2. Incident Number: (EON num. if applicable)		3. Date/Time Initiated: Date: _____ Time: _____	
10. Resource Summary:					
Resource	Resource Identifier	Date/Time Ordered	ETA	Arrived	Notes (location/assignment/status)
				<input type="checkbox"/>	
				<input type="checkbox"/>	
				<input type="checkbox"/>	
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				<input type="checkbox"/>	
				<input type="checkbox"/>	
				<input type="checkbox"/>	
6. Prepared by: Name: _____ Position/Title: _____ Signature: _____					
ICS 201, Page 4			Date/Time: _____		

Updated by FDA 2/2011

**Incident Objectives (ICS 202), Adapated for FDA**

1. Incident Name:	2. Operational Period: Date From: _____ Date To: _____ Time From: _____ Time To: _____															
3. Objective(s):																
4. Operational Period Command Emphasis:																
General Situational Awareness:																
5. Site Safety Plan Required? Yes <input type="checkbox"/> No <input type="checkbox"/> Approved Site Safety Plan(s) Located at:																
6. Incident Action Plan (the items checked below are included in this Incident Action Plan): <table style="width: 100%; border: none;"><tr><td style="width: 33%;"><input type="checkbox"/> ICS 203</td><td style="width: 33%;"><input type="checkbox"/> Map/Chart</td><td style="width: 34%;"><u>Other Attachments:</u></td></tr><tr><td><input type="checkbox"/> ICS 204</td><td><input type="checkbox"/> Weather Forecast/Tides/Currents</td><td><input type="checkbox"/> _____</td></tr><tr><td><input type="checkbox"/> ICS 205</td><td></td><td><input type="checkbox"/> _____</td></tr><tr><td><input type="checkbox"/> ICS 206</td><td></td><td><input type="checkbox"/> _____</td></tr><tr><td><input type="checkbox"/> ICS 208</td><td></td><td><input type="checkbox"/> _____</td></tr></table>		<input type="checkbox"/> ICS 203	<input type="checkbox"/> Map/Chart	<u>Other Attachments:</u>	<input type="checkbox"/> ICS 204	<input type="checkbox"/> Weather Forecast/Tides/Currents	<input type="checkbox"/> _____	<input type="checkbox"/> ICS 205		<input type="checkbox"/> _____	<input type="checkbox"/> ICS 206		<input type="checkbox"/> _____	<input type="checkbox"/> ICS 208		<input type="checkbox"/> _____
<input type="checkbox"/> ICS 203	<input type="checkbox"/> Map/Chart	<u>Other Attachments:</u>														
<input type="checkbox"/> ICS 204	<input type="checkbox"/> Weather Forecast/Tides/Currents	<input type="checkbox"/> _____														
<input type="checkbox"/> ICS 205		<input type="checkbox"/> _____														
<input type="checkbox"/> ICS 206		<input type="checkbox"/> _____														
<input type="checkbox"/> ICS 208		<input type="checkbox"/> _____														
7. Prepared by: Name: _____ Position/Title: _____ Signature: _____																
8. Approved by Incident Commander: Name: _____ Signature: _____																
ICS 202	IAP Page _____	Date/Time: _____														

Updated by FDA 2/2011



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**Organization Assignment List (ICS 203), Adapted for FDA**

1. Incident Name:		2. Operational Period: Date From: _____ Date To: _____ Time From: _____ Time To: _____	
3. Incident Commander(s)/Agency Incident Coordinator and Command Staff: (include location)		7. Operations Section:	
<input type="checkbox"/> IMT IC/UCs		Chief	
<input type="checkbox"/> IMG AIC		Deputy	
Deputy		Staging Area	
Safety Officer		Branch	
Public Info. Officer		Branch Director	
Liaison Officer		Deputy	
4. Agency/Organization Representatives:		Division/Group	
Agency/Organization	Name	Division/Group	
		Division/Group	
		Division/Group	
		Division/Group	
		Branch	
		Branch Director	
		Deputy	
5. Planning Section:		Division/Group	
Chief		Division/Group	
Deputy		Division/Group	
Resource Unit		Division/Group	
Situation Unit		Division/Group	
Documentation Unit		Branch	
Demobilization Unit		Branch Director	
Technical Specialists		Deputy	
		Division/Group	
		Division/Group	
		Division/Group	
6. Logistics Section:		Division/Group	
Chief		Division/Group	
Deputy			
Support Branch			
Director			
Supply Unit			
Facilities Unit		8. Finance/Administration Section:	
Ground Support Unit		Chief	
Service Branch		Deputy	
Director		Time Unit	
Communications Unit		Procurement Unit	
Medical Unit		Comp/Claims Unit	
Food Unit		Cost Unit	
9. Prepared by: Name: _____ Position/Title: _____ Signature: _____			
ICS 203	IAP Page _____	Date/Time: _____	

Updated by FDA 2/2011



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**Assignment List (ICS 204), Adapted for FDA**

1. Incident Name:		2. Operational Period: Date From: _____ Date To: _____ Time From: _____ Time To: _____		3. Branch: Division: Group:										
4. Operations Personnel: <table style="width: 100%;"><tr><td style="width: 60%;"><u>Name</u></td><td style="width: 40%;"><u>Contact Number(s)</u></td></tr><tr><td>Operations Section Chief: _____</td><td>_____</td></tr><tr><td>Branch Director: _____</td><td>_____</td></tr><tr><td>Division/Group Supervisor: _____</td><td>_____</td></tr></table>				<u>Name</u>	<u>Contact Number(s)</u>	Operations Section Chief: _____	_____	Branch Director: _____	_____	Division/Group Supervisor: _____	_____			
<u>Name</u>	<u>Contact Number(s)</u>													
Operations Section Chief: _____	_____													
Branch Director: _____	_____													
Division/Group Supervisor: _____	_____													
5. Resources Assigned:		# of Persons	Contact (e.g., phone, pager, radio frequency, etc.)	Reporting Location, Special Equipment and Supplies, Remarks, Notes, Information										
Resource Identifier	Leader													
6. Work Assignments:														
7. Special Instructions:														
8. Communications (radio and/or phone contact numbers needed for this assignment): <table style="width: 100%;"><tr><td style="width: 40%;"><u>Name/Function</u></td><td style="width: 60%;"><u>Primary Contact: indicate cell, pager, or radio (frequency/system/channel)</u></td></tr><tr><td>_____ / _____</td><td>_____</td></tr><tr><td>_____ / _____</td><td>_____</td></tr><tr><td>_____ / _____</td><td>_____</td></tr><tr><td>_____ / _____</td><td>_____</td></tr></table>					<u>Name/Function</u>	<u>Primary Contact: indicate cell, pager, or radio (frequency/system/channel)</u>	_____ / _____	_____	_____ / _____	_____	_____ / _____	_____	_____ / _____	_____
<u>Name/Function</u>	<u>Primary Contact: indicate cell, pager, or radio (frequency/system/channel)</u>													
_____ / _____	_____													
_____ / _____	_____													
_____ / _____	_____													
_____ / _____	_____													
9. Prepared by: Name: _____ Position/Title: _____ Signature: _____														
ICS 204	IAP Page _____	Date/Time: _____												

Updated by FDA 2/2011



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**Incident Communications Plan (ICS 205), Adapted for FDA**

1. Incident Name:		2. Date/Time Prepared: Date: _____ Time: _____		3. Operational Period: Date From: _____ Date To: _____ Time From: _____ Time To: _____	
4. Incident communication information:					
Incident Assigned Position	Name (Last, First)	Primary Number	Secondary Number	Other Method (s) of Contact (pager, email, radio, etc.)	Remarks
5. Special Instructions:					
6. Prepared by (Communications Unit Leader): Name: _____ Signature: _____					
ICS 205	IAP Page _____	Date/Time: _____			

Updated by FDA 2/2011



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**Medical Plan (ICS 206), Adapted for FDA**

1. Incident Name:		2. Operational Period: Date From: _____ Date To: _____ Time From: _____ Time To: _____				
3. Medical Aid Stations:						
Name	Location	Contact Number(s)/Frequency	Paramedics on Site? <input type="checkbox"/> Yes <input type="checkbox"/> No			
			<input type="checkbox"/> Yes <input type="checkbox"/> No			
			<input type="checkbox"/> Yes <input type="checkbox"/> No			
			<input type="checkbox"/> Yes <input type="checkbox"/> No			
			<input type="checkbox"/> Yes <input type="checkbox"/> No			
			<input type="checkbox"/> Yes <input type="checkbox"/> No			
4. Transportation:						
Ambulance Service	Location	Contact Number(s)/Frequency	Level of Service <input type="checkbox"/> ALS <input type="checkbox"/> BLS			
			<input type="checkbox"/> ALS <input type="checkbox"/> BLS			
			<input type="checkbox"/> ALS <input type="checkbox"/> BLS			
			<input type="checkbox"/> ALS <input type="checkbox"/> BLS			
5. Hospitals:						
Hospital Name	Address	Contact Number(s)	Distance	Trauma Center <input type="checkbox"/> Yes Level: _____	Burn Center <input type="checkbox"/> Yes <input type="checkbox"/> No	Helipad <input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes Level: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes Level: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes Level: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes Level: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Special Medical Emergency Procedures:						
7. Prepared by (Medical Unit Leader): Name: _____ Signature: _____						
8. Approved by (Safety Officer): Name: _____ Signature: _____						
ICS 206		IAP Page _____		Date/Time: _____		

Updated by FDA 2/2011



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Incident Check-In List (ICS 211), Adapted for FDA

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Resource Request (ICS 213 RR), Adapted for FDA

1. Incident Name:				2. Date/Time				3. Resource Request Number:			
Requestor	4. Order (Use additional forms when requesting different resource sources of supply.):										
	Qty.	Kind	Type	Detailed Item Description: (Vital characteristics, brand, specs, experience, size, etc.)	Cost	5. Resource Status					
						Received by	Date/Time	Assigned to	Released to	Date/Time	
6. Requested Delivery/Reporting Location:											
7. Suitable Substitutes and/or Suggested Sources:											
8. Requested by Name/Position:					9. Priority: <input type="checkbox"/> Urgent <input type="checkbox"/> Routine <input type="checkbox"/> Low		10. Section Chief Approval:				
Logistics	11. Logistics Order Number:					12. Supplier Phone/Fax/Email:					
	13. Name of Supplier/POC:										
	14. Notes:										
	15. Approval Signature of Auth Logistics Rep:					16. Date/Time:					
Finance	17. Order placed by:										
	18. Reply/Comments from Finance:										
	19. Finance Section Signature:					20. Date/Time:					

ICS 213 RR, Page 1

Updated by FDA 2/2011



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Operational Planning Worksheet (ICS 215)

1. Incident Name:										2. Operational Period:										Date From:		Date To:	
																				Time From:		Time To:	
3. Branch	4. Division, Group, or Other	5. Work Assignment & Special Instructions	6. Resources														7. Overhead Position(s)	8. Special Equipment & Supplies	9. Reporting Location	10. Requested Arrival Time			
			Req.																				
			Have																				
			Need																				
			Req.																				
			Have																				
			Need																				
			Req.																				
			Have																				
			Need																				
			Req.																				
			Have																				
			Need																				
			Req.																				
			Have																				
			Need																				
			Req.																				
			Have																				
			Need																				
ICS 215		11. Total Resources Required																14. Prepared by: Name: _____ Position/Title: _____ Signature: _____ Date/Time: _____					
		12. Total Resources Have on Hand																					
		13. Total Resources Need To Order																					



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**Incident Action Plan Safety Analysis (ICS 215A)**

1. Incident Name:		2. Incident Number:	
3. Date/Time Prepared: Date: _____ Time: _____		4. Operational Period: Date From: _____ Date To: _____ Time From: _____ Time To: _____	
5. Incident Area	6. Hazards/Risks	7. Mitigations	
8. Prepared by (Safety Officer): Name: _____ Signature: _____			
Prepared by (Operations Section Chief): Name: _____ Signature: _____			
ICS 215A		Date/Time: _____	



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**Demobilization Check-Out (ICS 221), Adapted for FDA**

1. Incident Name:		2. Incident (EON) Number:	
3. Planned Release Date/Time: Date: _____ Time: _____		4. Resource or Personnel Released:	
5. Order Request Number:			
6. Resource or Personnel: <input type="checkbox"/> IMT <input type="checkbox"/> IMG You and your resources are in the process of being released. Resources are not released until the checked boxes below have been signed off by the appropriate overhead and the Demobilization Unit Leader (or Planning Section representative).			
OPERATIONS SECTION			
	Division/Group Supervisor	Remarks	Name Signature
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			
PLANNING SECTION			
	Unit/Leader	Remarks	Name Signature
<input type="checkbox"/>	Situation Leader		
<input type="checkbox"/>	Documentation Leader		
<input type="checkbox"/>	Demobilization Leader		
<input type="checkbox"/>			
LOGISTICS SECTION			
	Unit/Leader	Remarks	Name Signature
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			
FINANCE/ADMINISTRATION SECTION			
	Unit/Leader	Remarks	Name Signature
<input type="checkbox"/>			
<input type="checkbox"/>			
OTHER SECTION/STAFF			
	Unit/Other	Remarks	Name Signature
<input type="checkbox"/>			
<input type="checkbox"/>			
7. Remarks:			
8. Travel Information:			
Estimated Time of Departure: _____		Room Overnight: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Destination: _____		Actual Release Date/Time: _____	
Travel Method: _____		Estimated Time of Arrival: _____	
Departure Location: _____		Contact Information While Traveling: _____	
Reservation, Flight, or Train Number: _____		Office/Center/Region/District Notified: _____	
9. Reassignment Information: <input type="checkbox"/> Yes <input type="checkbox"/> No			
Incident Name: _____		Incident Number: _____	
Location: _____		Order Request Number: _____	
10. Prepared by: Name: _____ Position/Title: _____ Signature: _____			
ICS 221		Date/Time: _____	

Updated by FDA 9/2013



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Situation Report

Template for creation of Situation Reports by FDA Incident Management Groups

FDA Situation Report	
Page Header Distributing Office (EOC)	
Title of Incident	FDA Situation Report Number
Date (DD/MM/YYYY)	Timeframe Report Covers (military time MM/DD/YYYY to MM/DD/YYYY) to
A. Executive Summary: <ul style="list-style-type: none">◆ A brief description of the incident◆ Initial and long-term response operations◆ The resources that were deployed, including whether specific resources were requested through the SOC, FEMA, mutual aid, or another mechanism◆ A description of key events and the timeframes of occurrence◆ Decisions that were made in response to events and the results◆ Issues that arose during the course of operations. Include those between or among MAC System entities, between the Incident Command and the EOC, and within the EOC.	
B. New Information:	
C. Investigations-Related Information and Other Data: <p>Data sources may include local, State, and other Federal Departments/Agencies. The following are examples of what data to report in this section.</p> <ul style="list-style-type: none">◆ Outbreak Data◆ Epidemiological Data◆ Lab Testing Data◆ Analytical Data<ul style="list-style-type: none">▪ Traceback Data▪ Traceforward Data▪ Assignments◆ Sampling Data	
D. Documentation Unit:	



FDA Situation Report (page 2)

E. Communications:

- ◆ Internal (within FDA)
- ◆ External (with other agencies, including HHS and CDC)
- ◆ Public Information (issuance of press releases; Consumer Health Information posted to FDA website; Call Center; outreach to patient, health professional and industry groups)

F. Strategic Objectives:

G. Additional Incident Response Information:

H. Prepared by:

I. Reviewed/Approved by:



Appendix K: Glossary of Terms

This appendix contains definitions of key terms as they are applied within the FDA EOP. All supporting agency emergency plans and procedural documentation shall be compliant with the terminology contained herein.

Term	Definition
Abbreviated New Drug Application (ANDA)	<p>An ANDA contains data that, when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provide for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low-cost alternative to the American public.</p> <p>A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use.</p> <p>Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug). One way scientists demonstrate bioequivalence is to measure the time it takes the generic drug to reach the bloodstream in 24 to 36 healthy volunteers. This gives them the rate of absorption, or bioavailability, of the generic drug, which they can then compare to that of the innovator drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug.</p> <p>The ANDA regulations can be found in Title 21 of the CFR Part 314, Subpart C.</p>
Activation	Implementation of an emergency plan, in whole or in part, in response to a confirmed report of an incident.
Agency Emergency Coordinator	Employees who serve as FDA's central emergency coordination point with FDA field offices, headquarters, and Centers and Federal, State, and local entities, including the CDC. They provide interagency coordination and response during adverse events, foodborne illnesses, injuries, product tampering, and manmade and natural disasters. In addition, they provide essential support and lead the agency proportional response to bioterrorism, shortage, and recall emergencies. They serve as a SME in the Incident Command System (ICS) and the National Incident Management System (NIMS).
Agency Executive Group (AEG)	The AEG is established when an emergency calls for the involvement of senior FDA officials with the knowledge and authority to address a wide range of issues that may arise. The AEG, whether convened as a collective unit or acting as individual members, serves primarily to provide strategic policy direction and guidance for major agency emergency response activities and to approve important policy decisions in consultation with the Commissioner and AIC when necessary.
Agency Incident Coordinator (AIC)	The individual responsible for the overall coordination of agency emergency management teams assigned. The AIC ensures that conflicts are resolved, incident objectives are established, and strategies are selected for the use of critical agency resources. He/she is also responsible for communicating with FDA headquarters and field organizational components and external Federal Agencies. The AIC reports directly to the AEG. Until an AIC is appointed by the Commissioner, Deputy Commissioner, or other designated senior agency official, the Director, OEO, within OCM, may serve as the AIC.
Alert	<p>Incident information without support. An alert is issued to agency emergency personnel when the following is received:</p> <ul style="list-style-type: none">▪ An unconfirmed report of a product-related illness/injury or unanticipated adverse reaction.▪ An unconfirmed report of the presence of a toxic (i.e., chemical, biological, radiological, or nuclear [CBRN]) substance.▪ A report of a natural (e.g., hurricane, flood, tornado) or manmade (e.g., oil spill, radiological accident) disaster.
All-Hazards	Describing an incident, natural or manmade, that warrants action to protect life, property, environment, and public health or safety and to minimize disruptions of government, social, or economic activities.
Antiviral	Drug that is used to prevent or cure a disease caused by a virus by interfering with the ability of the virus to multiply in number or spread from cell to cell.



Term	Definition
Avian Influenza	An infection caused by type A influenza viruses. These viruses occur naturally among birds worldwide, particularly waterfowl and shore birds. Wild birds are the natural reservoir of avian influenza viruses and carry the viruses in their intestines; they usually do not become ill from them. Infected birds shed influenza virus in their saliva, nasal secretions, and feces. Susceptible birds become infected when they have contact with contaminated excretions or with surfaces that are contaminated with excretions or secretions. Domesticated poultry may become infected with avian influenza virus through direct contact with infected waterfowl or other infected poultry or through contact with surfaces (such as dirt or cages) or materials (such as water or feed) that have been contaminated with the virus.
Becquerel (Bq)	A unit of radioactivity equivalent to one decay (disintegration) per second.
Catastrophic Incident	Any natural or manmade incident, including terrorism, that results in extraordinary levels of mass casualties, damage, or disruption severely affecting the population, infrastructure, environment, economy, national morale, and/or government functions.
Center/Office Emergency Coordinator	The staff member who has responsibility for Center/Office emergency management programs and activities. The role is one of coordinating all aspects of the Center's mitigation, preparedness, response, and recovery capabilities and serving in a liaison capacity between the Center/Office emergency management team and the Operations Section Chief. The Center Emergency Coordinator may serve as the AIC for all emergencies and disasters involving or affecting his/her product Center, unless otherwise directed.
Centers	FDA Product Centers: <ul style="list-style-type: none">Center for Biologics Evaluation and Research (CBER)Center for Drug Evaluation and Research (CDER)Center for Devices and Radiological Health (CDRH)Center for Food Safety and Applied Nutrition (CFSAN)Center for Veterinary Medicine (CVM)Center for Tobacco Products (CTP) FDA Research Center: <ul style="list-style-type: none">National Center for Toxicological Research (NCTR)
Centers for Disease Control and Prevention (CDC)	The U.S. Government Agency at the forefront of public health efforts to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental health threats. CDC is one of 13 major operating components of HHS.
Chief	The ICS title for individuals responsible for management of functional Sections: Operations, Planning, Logistics, and Finance/Administration.
Command Staff	The staff who report directly to the IC/AIC, including the Public Information Officer (PIO), Safety Officer, Liaison Officer (LNO), and other positions as required. They may have an assistant or assistants as needed.
Commissioner	The Commissioner of Food and Drugs.
Committed Dose	The cumulative dose to an individual's whole body or a specific organ resulting from continuous exposure to radioactive materials deposited inside the body, projected to either 50 or 70 years for an occupational worker or member of the general public, respectively.
Common Operating Picture	A continuously updated overview of an incident compiled throughout an incident's lifecycle from data shared between integrated systems for communication, information management, and intelligence and information sharing. The common operating picture allows agency headquarters and field personnel to make effective, consistent, and timely decisions.
Confirmed Report	Report that a problem has been confirmed through laboratory analyses, field investigations, analysis of epidemiological data, or a combination of these. Information received from another governmental agency or other source known to be reliable may be accepted for confirmation purposes.
Contamination (Radioactive)	The unexpected or undesired presence of radioactive material in or on the surfaces of structures, areas, objects, or people.
Cooperating Agency	Cooperating agencies include Federal Agencies that provide additional technical and resource support specific to nuclear/radiological incidents to DHS and the coordinating agencies.



Term	Definition
Coordinating Agency	Coordinating agencies provide the leadership, expertise, and authorities to implement critical and specific nuclear/radiological aspects of the response, and facilitate nuclear/radiological aspects of the response in accordance with those authorities and capabilities. The coordinating agencies are those Federal Agencies that own, have custody of, authorize, regulate, or are otherwise assigned responsibility for the nuclear/radioactive material, facility, or activity involved in the incident. These Federal Agencies have nuclear/radiological authorities, technical expertise, and/or assets for responding to the unique characteristics of nuclear/radiological incidents that are not otherwise described in the NRF.
Corrective Action	Implementing procedures that are based on lessons learned from actual incidents or from training and exercises.
Decay (Radioactive)	Disintegration of the nucleus of an unstable atom by the release of radiation.
Demobilization	The orderly, safe, and efficient return of agency resources to their original location and operating status. Demobilization signals the transition from the response phase of operations to recovery.
Deployment	The relocation of agency resources to desired operational areas. Deployment encompasses all activities from departing normal locations through arrival at destinations.
Division	The organizational level having responsibility for operations within a defined geographic area. Divisions are established within the Operations Section, at the headquarters level, to coordinate and monitor the operations of responding FDA Regions/Districts within a particular location and/or when a foreign country is involved.
Dose Coefficient	A factor used to convert radionuclide intake or content to radiation dose. One usually expresses it as dose per unit intake (e.g., sieverts [Sv] per becquerel).
Dose Equivalent	A quantity used in radiation protection to place all radiation on a common scale for calculating tissue damage. Dose equivalent is the absorbed dose in grays times a quality factor. The quality factor accounts for differences in radiation effects caused by different types of ionizing radiation. Some radiation, including alpha particles, causes a greater amount of damage per unit of absorbed dose than other radiation. The Sv is the unit that measures dose equivalent.
Dosimeter	A small portable instrument (e.g., a film badge, thermoluminescent dosimeter [TLD], or pocket dosimeter) for measuring and recording the total accumulated dose of ionizing radiation a person receives.
Effective Dose	A dosimetric quantity useful for comparing the overall health effects of irradiation of the whole body. It takes into account the absorbed doses received by various organs and tissues and weighs them according to present knowledge of the sensitivity of each organ to radiation. It also accounts for the type of radiation and the potential for each type to inflict biologic damage. Use the effective dose, for example, to compare the overall health detriments of different radionuclides in a given mix. The unit of effective dose is the Sv; 1 Sv = 1 joule per kilogram (J/kg).
Emergency	Any incident, whether natural or manmade, that requires responsive action to protect life or property. Under the Stafford Act, an emergency means any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States.
Emergency Management	The coordination and integration of all activities necessary to build, sustain, and improve the capability to prepare for, protect against, respond to, recover from, or mitigate against threatened or actual natural disasters, acts of terrorism, or other manmade emergencies.
Emergency Operations Plan (EOP)	An ongoing plan for responding to a wide variety of potential hazards.
Emergency Support Function (ESF)	Used by the Federal Government and many State governments as the primary mechanism at the operational level to organize and provide assistance. ESFs align categories of resources and provide strategic objectives for their use. ESFs utilize standardized resource management concepts such as typing, inventorying, and tracking to facilitate the dispatch, deployment, and recovery of resources before, during, and after an incident.
Emergency Support Function (ESF) Annexes	Annexes to the FDA EOP that present the missions, policies, structures, and responsibilities of FDA organizational components for coordinating resource and programmatic support to other Federal Agencies, States, territories, tribes, and local jurisdictions when NRF ESFs are activated during an incident.



Term	Definition
Emergency Use Authorization (EUA)	Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) permits the Commissioner of Food and Drugs to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces. The EUA authority allows FDA to strengthen the public health protections against CBRN agents that may be used to attack the American people or U.S. Armed Forces. Under Section 564 of the FD&C Act, the FDA Commissioner may allow medical countermeasures to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents when there are no adequate, approved, and available alternatives. Before FDA can issue an EUA, the HHS Secretary must declare an emergency justifying the authorization to use the product, based on one of three determinations: (1) a determination by the Secretary of Homeland Security of a domestic emergency, or the significant potential for a domestic emergency; (2) a determination by the Secretary of Defense of a military emergency, or the significant potential for a military emergency; or (3) a determination by the HHS Secretary of a public health emergency under the Public Health Service Act (PHSA).
Epidemic	A disease occurring suddenly in humans in a community, region, or country in numbers clearly in excess of normal. (See <i>Pandemic</i> .)
Exposure (Radiation)	A measure of ionization in air caused by x-rays or gamma rays only. The unit of exposure most often used is the roentgen (R).
Exposure Pathway	A route by which a radionuclide or other toxic material can enter the body. The main exposure routes are inhalation, ingestion, absorption through the skin, and entry through a cut or wound in the skin.
Finance/Administration Section	The ICS Section responsible for developing cost analyses and ensuring the IAP is within financial limits established by the Incident Commander. This Section also develops contracts and pays for resources.
Good Manufacturing Practice (GMP)	Manufacturers establish and follow quality systems to help ensure their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (food, drugs, biological products, and devices) are known as current GMPs, also seen as cGMP or CGMP. The GMP regulations for food are at 21 CFR Part 110. For human drugs and most biological products, the CGMP regulations are at 21 CFR Parts 210 and 211. For devices, the CGMP regulations are at 21 CFR Part 820 (quality system regulation).
Group	An organizational subdivision established to divide the incident management structure into functional areas of operation. Groups within the Operations Section, composed of headquarters personnel, are created to address similar emergency response activities.
Hazard	Something that is potentially dangerous or harmful, often the root cause of an unwanted outcome.
Headquarters	Includes all Offices within the OC, ORA, product Centers, and any divisions or branches therein.
Improvised Nuclear Device (IND)	An IND is an illicit nuclear weapon bought, stolen, or otherwise originating from a nuclear state, or a weapon fabricated by a terrorist group from illegally obtained fissile nuclear weapons material that produces a nuclear explosion. The nuclear yield achieved by an IND produces extreme heat, powerful shockwaves, and prompt radiation that would be acutely lethal for a significant distance. It also produces radioactive fallout, which may spread and deposit over very large areas. If a nuclear yield is not achieved, the result would likely resemble an RDD in which fissile weapons material was utilized.
Incident	An occurrence, natural or manmade, that requires a response to protect life or property. Incidents can, for example, include major disasters, emergencies, terrorist attacks, terrorist threats, civil unrest, wildland and urban fires, floods, HazMat spills, nuclear accidents, aircraft accidents, earthquakes, hurricanes, tornadoes, tropical storms, tsunamis, war-related disasters, public health and medical emergencies, and other occurrences requiring an emergency response.
Incident Action Plan (IAP)	An oral or written plan containing general objectives reflecting the overall agency strategy for managing an incident. It may include the identification of operational resources and assignments and/or attachments that provide direction and important information for management of the incident throughout its lifecycle. The Planning Section Chief, in coordination with other Incident Command and General Staff members, is responsible for developing the IAP.
Incident Annexes	Describe the concepts of operations to address specific hazards requiring specialized application of the FDA EOP.
Incident Command Post (ICP)	The field location where the primary functions are performed. The ICP may be collocated with the Incident Base or other incident facilities.

Term	Definition
Incident Command System (ICS)	A standardized on-scene emergency management construct designed to provide for the adoption of an integrated organizational structure that reflects the complexity and demands of single or multiple incidents, without being hindered by jurisdictional boundaries. ICS is designed to enable effective incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. It is used for all kinds of emergencies and is applicable to small as well as large and complex incidents. ICS is used by various jurisdictions and functional agencies, both public and private, to organize incident management operations.
Incident Commander (IC)	The individual responsible for all incident activities at the field level, including the development of strategies and tactics and the ordering and release of resources. The IC has overall authority and responsibility for conducting incident operations and is responsible for the management of all incident operations.
Influenza	A serious disease caused by viruses that infect the respiratory tract.
Investigational New Drug (IND) Application	<p>The IND regulations are at 21 CFR Part 312. Current Federal law requires that a new drug be the subject of an approved marketing application before it is transported or distributed across State lines unless the drug is shipped for investigational uses under an IND application. During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited early-stage clinical studies.</p> <p>FDA's role in the development of a new drug begins when the drug's sponsor (usually the manufacturer or potential marketer), having screened the new molecule for pharmacological activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the FD&C Act and becomes a new drug subject to specific requirements of the drug regulatory system.</p> <p>The IND application must contain information in three broad areas:</p> <ul style="list-style-type: none"> ▪ Animal Pharmacology and Toxicology Studies. Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included is any previous experience with the drug in humans (often foreign use). ▪ Manufacturing Information. Information pertaining to the composition, manufacture, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug. ▪ Clinical Protocols and Investigator Information. Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks and whether later stage trials are designed in a way to provide reliable evidence concerning effectiveness. Also, information on the qualifications of clinical investigators—professionals (generally physicians) who oversee the administration of the experimental compound—to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an Institutional Review Board (IRB), and to adhere to the IND regulations. <p>Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials unless FDA grants a waiver. During this time, FDA has an opportunity to review the IND for safety to ensure that research subjects will not be subjected to unreasonable risk.</p> <p>There are two general categories of INDs:</p> <ul style="list-style-type: none"> ▪ Commercial. An IND for which the sponsor intends for the product to be commercialized at some point. The sponsor for a commercial IND is generally a corporate entity or, in some cases, the National Institutes of Health (NIH) or an academic institution. ▪ Research (Noncommercial). An IND for which a study is being conducted for research purposes rather than commercial development. These INDs are generally sponsored by an individual investigator or an academic institution. <p>Within the two IND categories, there are several IND types.</p> <ul style="list-style-type: none"> ▪ Standard IND, while not a regulatory term, refers to an IND submitted as described under 21 CFR 312.23. Such an IND may be either a commercial or research IND. ▪ Emergency IND refers to when emergency use of an investigational drug is permitted by FDA based on telephone or other rapid communication request in some circumstances in which there is not time for submission of an IND application under the regulations. See 21 CFR 312.36. The term emergency IND is also, however, sometimes used to describe an IND that is specific to a particular patient and as to which use of the investigational drug is justified because alternative treatments are not available.



Term	Definition
	<ul style="list-style-type: none">▪ Treatment INDs, described under 21 CFR 312.34, are used to make promising new drugs available to desperately ill patients as early in the drug development process as possible. FDA will permit an investigational drug to be used under a treatment IND if there is preliminary evidence of drug efficacy and the drug is intended to treat a serious or life-threatening disease, or if there is no comparable alternative drug or therapy available to treat that stage of the disease in the intended patient population. In addition, these patients are not eligible to be in the definitive clinical trials, which must be well underway, if not almost finished.
Isolation	A state of separation between persons or groups to prevent the spread of disease. The first published recommendations for isolation precautions in U.S. hospitals appeared as early as 1877, when a handbook recommended placing patients with infectious diseases in separate facilities. Isolation measures can be undertaken in hospitals or homes, as well as in alternative facilities.
Joint Field Office (JFO)	The primary Federal incident management field structure. The JFO is a temporary Federal facility that provides a central location for the coordination of Federal and SLTT governments and private sector and nongovernmental organizations (NGOs) with primary responsibility for response and recovery. The JFO structure is organized, staffed, and managed in a manner consistent with NIMS principles and is led by a Unified Coordination Group. Although the JFO uses an ICS structure, the JFO does not manage on-scene operations. Instead, the JFO focuses on providing support to on-scene efforts and conducting broader support operations that may extend beyond the incident site.
Joint Information Center (JIC)	An interagency entity established to coordinate and disseminate information for the public and media concerning an incident. JICs may be established locally, regionally, or nationally depending on the size and magnitude of the incident.
Lead District	The FDA District Office with primary responsibility for addressing an incident. For the majority of incidents involving FDA-regulated products, the District in which the event is occurring (e.g., the physical location where people have been affected) will generally assume the lead District role.
Liaison Officer (LNO)	A member of the Command Staff responsible for coordinating with external Federal Agencies (i.e., HHS, CDC, USDA, DHS, FBI, or DOS). LNOs serve as direct links between the AIC and their assigned agencies, and work as members of the external agencies' EOCs, providing input on FDA policies, activities, concerns, resource availability, and other incident-related matters.
Logistics Section	Section responsible for providing facilities, services, and material support for the incident.
Major Disaster	Under the Stafford Act, any natural catastrophe (including any hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought) or, regardless of cause, any fire, flood, or explosion in any part of the United States that, in the determination of the President, causes damage of sufficient severity and magnitude to warrant major disaster assistance under the Stafford Act to supplement the efforts and available resources of States, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused thereby.
Memorandum of Understanding (MOU)	A formal agreement between FDA and another government agency (Federal, State, or local) or private institution, or an informal agreement with foreign governments or other foreign institutions.
Mission Assignment (MA)	A task given to an agency component to perform within a given operational period that is based on operational objectives defined in the IAP.
National Disaster Medical System (NDMS)	<p>A federally coordinated system that augments the Nation's medical response capability. The overall purpose of the NDMS is to supplement an integrated national medical response capability for assisting State and local authorities in dealing with the medical impacts of major peacetime disasters and to provide support to the military and the U.S. Department of Veterans Affairs (VA) medical systems in caring for casualties evacuated back to the United States from overseas armed conventional conflicts.</p> <p>The NRF uses the NDMS, as part of HHS/ASPR, under ESF #8 – Public Health and Medical Services, to support Federal Agencies in the management and coordination of the Federal medical response to major emergencies and federally declared disaster, including:</p> <ul style="list-style-type: none">▪ Natural Disasters▪ Major Transportation Accidents▪ Technological Disasters▪ Acts of Terrorism, including WMD events
National Disaster Recovery Framework (NDRF)	Serves as guide to enable effective recovery support to disaster-impacted SLTT jurisdictions. It provides a flexible structure that enables disaster recovery managers to operate in a unified and collaborative manner. It also focuses on how best to restore, redevelop, and revitalize the health, social, economic, natural, and environmental fabric of the community and build a more resilient Nation.



Term	Definition
National Incident Management System (NIMS)	Provides a systematic, proactive approach to guide departments and agencies at all levels of government, NGOs, and the private sector to work seamlessly to prevent, protect against, respond to, recover from, and mitigate the effects of incidents, regardless of cause, size, location, or complexity, to reduce the loss of life and property and harm to the environment. NIMS works hand-in-hand with the NRF. It provides the template for the management of incidents, while the NRF provides the structure and mechanisms for national-level policy for incident management.
National Infrastructure Protection Plan (NIPP)	Plan that provides a coordinated approach to critical infrastructure and key resources (CIKR) protection for Federal, State, tribal, local, and private sector security partners. It sets national priorities, goals, and requirements for effective distribution of funding and resources that will help ensure that our Government, economy, and public services continue in the event of a terrorist attack or other disaster.
National Operations Center (NOC)	Serves as the primary national hub for situational awareness and operations coordination across the Federal Government for incident management. The NOC provides the Secretary of Homeland Security and other principals with information necessary to make critical national-level incident management decisions.
National Preparedness Guidelines	Guidance that establishes a vision for national preparedness and provides a systematic approach for prioritizing preparedness efforts across the Nation. These guidelines focus policy, planning, and investments at all levels of government and the private sector.
National Response Framework (NRF)	Guides how the Nation conducts all-hazards response. The NRF documents the key response principles, roles, and structures that organize national response. It describes how communities, States, the Federal Government, and private sector and nongovernmental partners apply these principles for a coordinated, effective national response. Also, it details special circumstances where the Federal Government exercises a larger role, including incidents where Federal interests are involved and catastrophic incidents where a State would require significant support. The NRF allows first responders, decision makers, and supporting entities to provide a unified national response.
National Terrorism Advisory System (NTAS)	The NTAS communicates information about terrorist threats by providing timely, detailed information to the public, government agencies, first responders, airports and other transportation hubs, and the private sector. <ul style="list-style-type: none">▪ An <i>Elevated Threat Alert</i> warns of credible nonspecific terrorist threat against the United States.▪ An <i>Imminent Threat Alert</i> warns of credible, specific, and impending terrorist threat against the United States.
New Drug Application (NDA)	The NDA is the vehicle through which drug sponsors formally propose that FDA approve a new pharmaceutical for sale and marketing in the United States. The data gathered during the animal studies and human clinical trials of an IND become part of the NDA. The goals of the NDA are to provide enough information to permit the FDA reviewer to reach the following key decisions: <ul style="list-style-type: none">▪ Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.▪ Whether the drug's proposed labeling (package insert) is appropriate and what it should contain.▪ Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical trials, the ingredients of the drug, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed, and packaged. The NDA regulations are at 21 CFR Part 314.
Nuclide	A general term applicable to all atomic forms of an element. The number of protons and neutrons in the nucleus and the amount of energy contained within the atom characterize nuclides.
Offices	Refers to the collective FDA headquarters and field offices, including those of the OC and ORA.



Term	Definition
Operating Division (OPDIV)	Agencies within HHS. HHS OPDIVs include FDA and the following: <ul style="list-style-type: none">Administration for Children and Families (ACF)Administration on Aging (AoA)Agency for Healthcare Research and Quality (AHRQ)Agency for Toxic Substances and Disease Registry (ATSDR)Centers for Disease Control and Prevention (CDC)Centers for Medicare & Medicaid Services (CMS)Health Resources and Services Administration (HRSA)Indian Health Service (IHS)National Institutes of Health (NIH)Substance Abuse and Mental Health Services Administration (SAMHSA)
Operations Section	The ICS Section responsible for all tactical incident operations and implementation of the IAP. In ICS, the Operations Section normally includes subordinate branches, divisions, and/or groups.
Organizational Component	As defined by <i>FDA Staff Manual Guide</i> (SMG) 1005.1, "FDA Organizational Changes – Policy, Policy Regarding Organizational Changes," any part of the FDA organization that is separately established as an organizational entity by law, regulation, the Secretary, or an official who has been delegated authority and that has formally assigned functions and an approved Standard Administrative Code and title. FDA organizational components include all Centers, Offices, divisions, branches, and resident posts at the headquarters and field levels.
Pandemic	The worldwide outbreak of a disease in humans in numbers clearly in excess of normal. (See <i>Epidemic</i> .)
Planning Section	The ICS Section responsible for the collection, evaluation, and dissemination of operational information related to the incident and for the preparation and documentation of the IAP. This Section also maintains information on the current and forecasted situation and on the status of resources assigned to the incident.
Plume	The material spreading from a particular source and traveling through environmental media such as air or ground water. For example, a plume could describe the dispersal of particles, gases, vapors, and aerosols in the atmosphere or the movement of contamination through an aquifer (e.g., dilution, mixing, or adsorption onto soil).
Preparedness	Actions that involve a combination of planning, resources, training, exercising, and organizing to build, sustain, and improve operational capabilities. Preparedness is the process of identifying the personnel, training, and equipment needed for a wide range of potential incidents and developing specific plans for the delivery of agency capabilities. While not part of the phases of FDA emergency operations, preparedness ensures that agency resources are available and effectively implemented when needed.
Presidential Policy Directive 8 (PPD-8): National Preparedness	Directive for the development of a national preparedness goal and national preparedness system. PPD-8 is designed to facilitate an integrated all-of-Nation/whole community capabilities-based approach to preparedness.
Presumptive	Used to describe information that strongly suggests a problem exists. Presumptive information consists of: <ul style="list-style-type: none">Epidemiological data that provides a significant association between an illness, injury, or unanticipated adverse reaction and a product.An original analysis by a reliable laboratory revealing a significant level of a toxic substance in a regulated product, but confirmation is not complete.Natural or manmade incident reporting the extent of which is unknown at the present time.
Prevention	Actions to avoid an incident or to intervene to stop an incident from occurring. It involves applying intelligence and other information to a range of activities that may include such countermeasures as deterrence operations, heightened inspections, investigations to determine the full nature and source of the threat, public health and agricultural surveillance and testing processes, and, as appropriate, specific law enforcement operations aimed at deterring, preempting, interdicting, or disrupting illegal activity and apprehending potential perpetrators and bringing them to justice.
Protection	Actions to mitigate the overall risk to FDA-regulated products resulting from accidental or intentional contamination/adulteration. Protection includes actions to deter the threat, mitigate vulnerabilities, or minimize consequences associated with a terrorist attack or other potential incident.
Public Health	The science and practice of protecting and improving the overall health of the community through disease prevention and early diagnosis, control of communicable diseases, health education, injury prevention, sanitation, and protection from environmental hazards.



Term	Definition
Public Health Emergency	Pursuant to Section 319 of the PHSA, a determination by the HHS Secretary that a disease or disorder presents a public health risk, including significant outbreaks of infectious diseases or bioterrorist attacks. Existence of a public health emergency authorizes the Secretary to take certain actions appropriate to respond to the incident or potential incident, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder.
Public Information Officer (PIO)	A member of the Command Staff responsible for managing incident-related information requirements. The PIO coordinates development and release of agency public health and consumer protection messages for use with the public, media, and/or other agencies with approval from FDA headquarters and HHS.
Quarantine	<p>The period of isolation decreed to control the spread of disease. Before the era of antibiotics, quarantine was one of the few available means of halting the spread of infectious disease. It is still employed today as needed. The list of quarantinable diseases in the United States is established by Executive Order of the President, on recommendation of the HHS Secretary, and includes cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, and viral hemorrhagic fevers (such as Marburg, Ebola, and Congo-Crimean disease).</p> <p>In 2003, severe acute respiratory syndrome (SARS) was added as a quarantinable disease. In 2005, another disease was added to the list, influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic.</p>
Radiation	Energy moving in the form of particles or waves. Familiar radiations are heat, light, radio waves, and microwaves. Ionizing radiation is a very high-energy form of electromagnetic radiation.
Radioactive Contamination	The deposition of unwanted radioactive material on the surfaces of structures, areas, objects, or people. It can be airborne, external, or internal.
Radioisotope (Radioactive Isotope)	Isotopes of an element that have an unstable nucleus. Science, industry, and medicine commonly use radioactive isotopes. The nucleus eventually reaches a stable number of protons and neutrons through one or more radioactive decays. Roughly 3,700 natural and artificial radioisotopes have been identified.
Radiological Dispersal Device (RDD)	A device that disperses radioactive material by conventional explosive or other mechanical means, such as a spray.
Radionuclide	An unstable and therefore radioactive form of a nuclide.
Recovery (Short Term)	The transition from emergency response back to normal operations. During the short-term recovery phase, FDA analyzes the cause of the incident to minimize the chance of the incident, emergency, or crisis reoccurring and repairs any strained relationships with stakeholders. The agency also assesses the actions taken to resolve the incident and addresses any short- or long-term effects. As a result, agency policies, plans, and procedures are updated, incorporating lessons learned from the event.
Resources	Personnel and major items of agency equipment, supplies, and facilities available or potentially available for assignment to incident operations and for which status is maintained.
Response	<p>Immediate actions to protect consumers and ensure the safety of FDA-regulated products. Response also includes the execution of agency emergency plans and procedures and actions to support and mitigation of short-term recovery.</p> <p>Response activities may include applying intelligence and other information to lessen the effects or consequences of an incident; investigations into nature and source of the threat; ongoing public health and product surveillance and testing processes; and law enforcement operations aimed at preempting, interdicting, or disrupting illegal activity; and apprehending actual perpetrators and bringing them to justice.</p>
Secretary	Secretary of the U.S. Department of Health and Human Services (HHS).
Shelf Life Extension Program (SLEP)	DoD, the CDC, and VA maintain significant reserves of critical medical supplies. CDC maintains its reserves in the SNS. These supplies include drug products that have expiration dates. Constantly replacing drug products as they reach their expiration dates can be quite costly. To reduce overall costs to the Federal Government and to the taxpayer, DoD, CDC, and VA work with FDA to determine whether a drug product's useful life can be extended beyond the expiration date. FDA tests samples of specified lots of stored drug products submitted by participating Federal entities and analyzes the data to determine whether the data are adequate to allow for the use of product beyond the expiration date on the product labeling. The stored drug products are to be maintained under each product's labeled storage conditions.
Shielding	The use of material placed between a radiation source and an individual to reduce exposure.



Term	Definition
Sievert (Sv)	A unit of dose equivalent. This relates the absorbed dose in human tissue to the effective biological damage of the radiation. Not all radiation has the same biological effect, even for the same amount of absorbed dose. Dose equivalent is often expressed as millionths of a Sv, or microsievert (μSv). One Sv is equivalent to 100 roentgen equivalent man (rem).
Situation Report (SitRep)	A situation report or SitRep is a document that contains confirmed or verified information regarding the specific details relating to an incident. It provides explicit details (who, what, when, where, and how) of an incident.
Situational Awareness	The ability to identify, process, and comprehend the critical elements of information about an incident.
Stakeholder	Any person or entity involved in or affected by an FDA course of action. Stakeholders include consumers, FDA employees, vendors, and external government agencies.
Standard Operating Procedure (SOP)	A complete reference document or an operations manual that provides the purpose, authorities, duration, and details for the preferred method of performing a single function or a number of interrelated functions in a uniform manner.
Status Report	Information specifically related to the availability or assignment of agency resources. Status reports are used by Center, Regional, and/or District emergency coordinators to provide FDA senior officials with real-time information on the status of agency resources (i.e., personnel, facilities, equipment, and other materials) impacted by an incident and/or those deployed in support of emergency response operations. FDA status reports generally come in the form of daily teleconferences, or more frequently depending on situation requirements, sponsored by the Planning Section Chief.
Strategic National Stockpile (SNS)	The SNS is a national repository of vaccines, antivirals, antibiotics, chemical antidotes, antitoxins, life-support medications, intravenous administration, airway maintenance supplies, and medical/ surgical items. The SNS is designed to supplement and resupply State and local public health agencies in the event of a national emergency anywhere and at anytime within the United States or its territories.
Surveillance and Detection	The ongoing, systematic collection, analysis, and interpretation of public health data essential to the planning, execution, and evaluation of FDA emergency operations closely integrated with the timely dissemination of these data to those responsible for prevention and control.
Technical Specialists	Person with special skills that can be used anywhere within the ICS organization. No minimum qualifications are prescribed, as Technical Specialists normally perform the same duties during an incident that they perform in their everyday jobs.
Terrorism	As defined under the Homeland Security Act of 2002, any activity that involves an act dangerous to human life or potentially destructive of CIKR; is a violation of the criminal laws of the United States or of any State or other subdivision of the United States in which it occurs; and is intended to intimidate or coerce the civilian population or influence or affect the conduct of a government by mass destruction, assassination, or kidnapping.
Threat	An indication of possible violence, harm, or danger.
Unified Command (UC)	An ICS application used when more than one agency has incident jurisdiction or when incidents cross political jurisdictions. Agencies work together through the designated members of the UC, often the senior persons from agencies and/or disciplines participating in the UC, to establish a common set of objectives and strategies and a single IAP.
Vaccine	A preparation consisting of antigens of a disease-causing organism that, when introduced into the body, stimulates the production of specific antibodies or altered cells. This produces immunity to the disease-causing organism. The antigen in the preparation can be whole disease-causing organisms (killed or weakened) or parts of these organisms.
Virus	Any of various simple submicroscopic parasites of plants, animals, and bacteria that often cause disease and that consist essentially of a core of ribonucleic acid (RNA) or deoxyribonucleic acid (DNA) surrounded by a protein coat. Unable to replicate without a host cell, viruses are typically not considered living organisms.
Warning Letter	A Warning Letter is a written communication from FDA notifying an individual or firm that the agency considers one or more products, practices, processes, or other activities to be in violation of the FD&C Act or other relevant statutes, and that failure of the responsible party to take appropriate and prompt action to correct and prevent any future repeat of the violation may result in administrative and/or regulatory enforcement action without further notice.
World Health Organization (WHO)	An agency of the United Nations established in 1948 to further international cooperation in improving health conditions.

Appendix L: List of Acronyms and Abbreviations

This appendix provides the meaning of acronyms and abbreviations used in the FDA EOP.

Acronym/ Abbreviation	Definition
µg/kg	Microgram Per Kilogram
µSv	Microsievert
24/7	24 Hours a Day, 7 Days a Week
A&F	Administration and Finance [HHS/ASPR]
AABB	American Association of Blood Banks
AAR	After Action Report
ACCP	Assistant Commissioner for Compliance Policy
ACF	Administration for Children and Families [HHS]
ACO	Assistant Commissioner for Operations
ACOMS	Advisory Committee Oversight and Management Staff
ACRA	[Office of the] Associate Commissioner for Regulatory Affairs [ORA]
ADE	Adverse Drug Experience
Advisory Team	Advisory Team for Environment, Food, and Health
AEG	Agency Executive Group
AERS	Adverse Event Reporting System
AHRQ	Agency for Healthcare Research and Quality [HHS]
AIC	Agency Incident Coordinator
ALC	Agency Location Code
Am	Americium
AMS	Agricultural Marketing Service [USDA]
ANDA	Abbreviated New Drug Application
AoA	Administration on Aging [HHS]
ARF	Action Request Form
ASL	[Office of the] Assistant Secretary for Legislation [HHS]
ASPA	[Office of the] Assistant Secretary for Public Affairs [HHS]
ASPR	[Office of the] Assistant Secretary for Preparedness and Response [HHS]
ATCC	American Type Culture Collection
ATS	Automated Targeting System [DHS/CBP]
ATSDR	Agency for Toxic Substances and Disease Registry [HHS]
BARDA	Biomedical Advanced Research and Development Authority
BASIS	Blood Availability and Safety Information System
BDPR	Biological Product Deviation Reporting
Bioterrorism Act	Public Health Security and Bioterrorism Preparedness and Response Act of 2002
BPDR	Biological Product Deviation Reporting
Bq	Becquerel
Bq/kg	Becquerel Per Kilogram
CAERS	CFSAN [Center for Food Safety and Applied Nutrition] Adverse Event Reporting System
CAN	Counterfeit Alert Network
CBER	Center for Biologics Evaluation and Research
CBP	U.S. Customs and Border Protection [DHS]
CBRN	Chemical, Biological, Radiological, and Nuclear
CBRNE	Chemical, Biological, Radiological, Nuclear, and High-Yield Explosive(s)



Acronym/ Abbreviation	Definition
CC	Collaborating Centre [WHO]
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CEC	Center Emergency Coordinator
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
cGMP or CGMP	Current Good Manufacturing Practice
CIKR	Critical Infrastructure and Key Resources
CMO	Chief Medical Officer
CMS	Centers for Medicare & Medicaid Services [HHS]
COBOP	Continuity of Business Operations Plan
CONOPS	Concept of Operations
COOP	Continuity of Operations
CORE	Coordinated Outbreak Response and Evaluation
CPG	Comprehensive Preparedness Guide
CPGM	Compliance Program Guidance Manual
Cs	Cesium
CSR	CDER [Center for Drug Evaluation and Research] Situation Room
CTP	Center for Tobacco Products
CVM	Center for Veterinary Medicine
DACRA	Deputy Associate Commissioner for Regulatory Affairs
DD	District Director
DEOC	Director's Emergency Operations Center
DERC	District Emergency Response Coordinator
DFAS	Defense Financial Accounting Center
DFDT	Division of Food Defense Targeting
DFI	Division of Field Investigations [ORA]
DFO	Division of Financial Operations [HHS/PSC]
DHS	U.S. Department of Homeland Security
DIB	Director, Investigations Branch
DIL	Derived Intervention Level
DIOP	Division of Import Operations and Policy
DMPTI	Division of Medical Products and Tobacco Inspections
DMPTPO	Division of Medical Products and Tobacco Program Operations
DNA	Deoxyribonucleic Acid
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
DOI	U.S. Department of the Interior
DOJ	U.S. Department of Justice
DOL	U.S. Department of Labor
DOS	U.S. Department of State
DUNS	Data Universal Numbering System
EIN	Employer Identification Number
eLEXNET	Electronic Laboratory Exchange Network
EMEA	European Medicines Agency
EMG	Emergency Management Group
EOC	Emergency Operations Center



Acronym/ Abbreviation	Definition
EON-IMS	Emergency Operations Network – Incident Management System
EOP	Emergency Operations Plan
EPA	U.S. Environmental Protection Agency
EPEES	Emergency Planning, Exercises, and Evaluation Staff
Epi-X	Epidemic Information Exchange
ERCG	Emergency Response Coordination Group
ERIC	Employee Resource and Information Center
ERL	Essential Regulatory Laboratory [WHO]
ERP	Emergency Response Plan
ESEMS	Employee Safety and Environmental Management Staff [OO]
ESF	Emergency Support Function
EUA	Emergency Use Authorization
FACTS	Field Accomplishments and Compliance Tracking System
FATA	Federal Anti-Tampering Act
FBI	Federal Bureau of Investigation
FCC	Forensic Chemistry Center
FD&C Act	Federal Food, Drug, and Cosmetic Act [of 1938]
FDA	U.S. Food and Drug Administration
FDRC	Federal Disaster Recovery Coordinator
FEMA	Federal Emergency Management Agency
FERN	Food Emergency Response Network
FOH	Federal Occupational Health [USPHS]
FOIA	Freedom of Information Act
FoodNet	Foodborne Diseases Active Surveillance Network
FRMAC	Federal Radiological Monitoring and Assessment Center
FRPCC	Federal Radiological Preparedness Coordinating Committee
FSIS	Food Safety and Inspection Service [USDA]
FSMA	Food Safety Modernization Act [of 2011] [FDA]
FTC	Federal Trade Commission
FVM	Foods and Veterinary Medicine
GCC	Government Coordination Council
GCP	Good Clinical Practice
GETS	Government Emergency Telecommunications Service
GIS	Geographic Information System
GISN	Global Influenza Surveillance Network [WHO]
GISRS	Global Influenza Surveillance and Response System [WHO]
GMP	Good Manufacturing Practice
GSA	U.S. General Services Administration
HAN	Health Alert Network
HazMat	Hazardous Material(s)
HHS	U.S. Department of Health and Human Services
HR	Human Resources
HRSA	Health Resources and Services Administration [HHS]
HSC	Homeland Security Council
HSIN	Homeland Security Information Network
HSP	Human Subject Protection
HSPD	Homeland Security Presidential Directive
HUS	Hemolytic Uremic Syndrome



Acronym/ Abbreviation	Definition
I	Iodine
IAG	Interagency Agreement
IAP	Incident Action Plan
IC	Incident Commander
ICLN	Integrated Consortium of Laboratory Networks
ICP	Incident Coordination Plan Incident Command Post
ICS	Incident Command System
IDE	Investigational Device Exemption
IFMIS	Integrated Financial Management Information System
IHR	International Health Regulations [WHO]
IHS	Indian Health Service [HHS]
IMAAC	Interagency Modeling and Atmospheric Center
IMG	Incident Management Group
IMPAC	International Merchant Purchase Authorization Card
IMS	Incident Management System
IMT	Incident Management Team
IND	Improvised Nuclear Device Investigational New Drug
IPAC	Intra-Governmental Payment and Collection
IRB	Institutional Review Board
IRCT	Incident Response Coordination Team
ISDN	Integrated System Digital Network
ISP	Internet Service Provider
IT	Information Technology
IVD	In-Vitro Diagnostics
J/kg	Joule Per Kilogram
JFO	Joint Field Office
JIC	Joint Information Center
JIS	Joint Information System
JOC	Joint Operations Center
LAN	Local Area Network
LDO	Late Duty Officer
LDRM	Local Disaster Recovery Manager
LNO	Liaison Officer
LRN	Laboratory Response Network
MA	Mission Assignment
MAC	Multiagency Coordination
MAC-FIO	Multiagency Coordination Group for Foodborne Illness Outbreaks
MAUDE	Manufacturer and User Facility Device Experience [System]
MCMi	Medical Countermeasures Initiative
MedSun	Medical Product Surveillance Network
MFRPS	Manufactured Food Regulatory Program Standards
ML	Mobile Laboratory
MOU	Memorandum of Understanding
mSv	Millisievert
NARAC	National Atmospheric Release Advisory Center
NASA	National Aeronautics and Space Administration



Acronym/ Abbreviation	Definition
NBIC	National Biosurveillance Integration Center [DHS]
NBIS	National Biosurveillance Integration System
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NCS	National Communications System
NCTC	National Counterterrorism Center
NCTR	National Center for Toxicological Research
NDA	New Drug Application
NDMS	National Disaster Medical System
NDRF	National Disaster Recovery Framework
NGO	Nongovernmental Organization
NICCL	National Incident Communications Conference Line
NIH	National Institutes of Health [HHS]
NIMS	National Incident Management System
NIPP	National Infrastructure Protection Plan
NJTTF	National Joint Terrorism Task Force [FBI]
NNSA	National Nuclear Security Agency [DOE]
NOAA	National Oceanic and Atmospheric Administration
NOC	National Operations Center [DHS]
NPG	National Preparedness Goal
NRC	U.S. Nuclear Regulatory Commission
NRCC	National Response Coordination Center
NRF	National Response Framework
NRF-CIA	National Response Framework Catastrophic Incident Annex
NRF-CIS	National Response Framework Catastrophic Incident Supplement
NRIA	Nuclear/Radiological Incident Annex [NRF]
NRP	National Response Plan
NSIS	National Strategy for Information Sharing
NSPD	National Security Presidential Directive
NSSE	National Special Security Event
NTAS	National Terrorism Advisory System
NVPO	National Vaccine Program Office
OAGS	Office of Acquisitions and Grants Services
OB	Office of Budget
OBS	Office of Business Services
OC	Office of the Commissioner
OCC	Office of the Chief Counsel
OCET	Office of Counterterrorism and Emerging Threats
OCHA	Office of Health and Constituent Affairs [OEA]
OCI	Office of Criminal Investigations
OCM	Office of Crisis Management
OCoS	Office of the Chief of Staff
OCP	Office of Combination Products
OCQPM	Office of Communication and Quality Program Management
OCS	Office of the Chief Scientist
OEA	Office of External Affairs
OEO	Office of Emergency Operations
OES	Office of the Executive Secretariat
OFBA	Office of Finance, Budget, and Acquisition



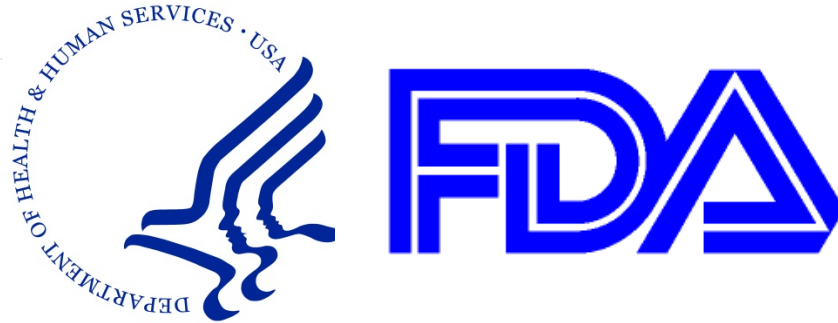
Acronym/ Abbreviation	Definition
OFEMS	Office of Facilities Engineering and Mission Support Services
OFFO	Office of Food and Feed Operations
OFM	Office of Financial Management
OFO	Office of Financial Operations
OFVM	Office of Foods and Veterinary Medicine
OGC	Office of the General Counsel [HHS]
OGCP	Office of Good Clinical Practice
OGROP	Office of Global Regulatory Operations and Policy
OHR	Office of Human Resources
OIEO	Office of Enforcement and Import Operations
OIM	Office of Information Management
OIP	Office of International Programs
OL	Office of Legislation
OM	Office of Management
OMA	Office of Media Affairs
OMB	Office of Management and Budget
OMPT	Office of Medical Products and Tobacco
OMPTO	Office of Medical Products and Tobacco Operations
OO	Office of Operations
OP	Office of Partnerships
OPDIV	Operating Division
OPM	Office of Personnel Management
OPP	Office of Policy and Planning
OPRM	Office of Policy and Risk Management
OPT	Office of Pediatric Therapeutics
ORA	Office of Regulatory Affairs
ORM	Office of Resource Management
ORO	Office of Regional Operations
ORS	Office of Regulatory Science
OSHA	Occupational Safety and Health Administration
OSMP	Office of Special Medical Programs
OSO	Office of Security Operations
OSS	Office of Shared Services
OWA	Outlook Web Access
PAC	Program Account Code
PAG	Protective Action Guide
PAR	Protective Action Recommendation
PC	Personal Computer
P-card	Purchase Card
pCi	Picocuries
pCi/kg	Picocuries Per Kilogram
PCR	Polymerase Chain Reaction
PETNet	Pet Event Tracking Network
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHSA	Public Health Service Act
PICCL	Private Sector Incident Communications Conference Line
PIN	Personal Identification Number
PIO	Public Information Officer



Acronym/ Abbreviation	Definition
POC	Point of Contact
POCS	Program Operations and Coordination Staff
PPD	Presidential Policy Directive
PPE	Personal Protective Equipment
PREP Act	Public Readiness and Emergency Preparedness Act [of 2005]
PSC	Program Support Center [HHS]
PSMA	Pre-Scripted Mission Assignment
Pu	Plutonium
Q&A	Question and Answer
R	Roentgen
RDD	Radiological Dispersal Device
REC	Regional Emergency Coordinator [HHS]
REE	Research, Education, and Economics [USDA]
rem	Roentgen Equivalent Man
RERC	Regional Emergency Response Coordinator
RES	Recall Enterprise System
RFDD	Regional Food and Drug Director
RFI	Request for Information
RFR	Reportable Food Registry
RHRC	Rockville Human Resources Center [HHS]
RNA	Ribonucleic Acid
RRCC	Regional Response Coordination Center [DHS/FEMA]
RRHR	Regional Radiological Health Representative
RRT	Rapid Response Team
RSA	Remote Secure Access
RSF	Recovery Support Function
RSS	Really Simple Syndication
Ru	Ruthenium
SAIC	Special Agent in Charge
SAMHSA	Substance Abuse and Mental Health Services Administration [HHS]
SARS	Severe Acute Respiratory Syndrome
SDRC	State Disaster Recovery Coordinator
SICCL	State Incident Communications Conference Line
SitRep	Situation Report
SLEP	Shelf Life Extension Program
SLG	State and Local Guide
SLTT	State, Local, Tribal, and Territorial
SME	Subject Matter Expert
SMG	Staff Manual Guide [FDA]
SNS	Strategic National Stockpile
SOC	Secretary's Operations Center [HHS]
SOP	Standard Operating Procedure
Sr	Strontium
SRAS	Secure Remote Access System
SSP	Sector-Specific Plan
Stafford Act	Robert T. Stafford Disaster Relief and Emergency Assistance Act
Sv	Sievert
TCL	Target Capabilities List



Acronym/ Abbreviation	Definition
TDRRC	Tribal Disaster Recovery Coordinator
TLD	Thermoluminescent Dosimeter
U.S.C.	United States Code
UC	Unified Command
UFMS	Unified Financial Management System
USCG	U.S. Coast Guard
USDA	U.S. Department of Agriculture
USG	U.S. Government
USPHS	U.S. Public Health Service
USPS	U.S. Postal Service
UTL	Universal Task List
VA	U.S. Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VET-LRN	Veterinary Laboratory Response Network
VoIP	Voice over Internet Protocol
WAN	Wide Area Network
WEAC	Winchester Engineering and Analytical Center
WHO	World Health Organization
WMD	Weapon(s) of Mass Destruction
WPS	Wireless Priority Service
wt	Wild-Type



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. Food and Drug Administration**

Nuclear/Radiological Annex to the FDA Emergency Operations Plan

Version 2.0

March 2014

OFFICE OF CRISIS MANAGEMENT

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RECORD OF CHANGES

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NOTE: See individual annexes for additional record of changes.



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NUCLEAR/RADIOLOGICAL ANNEX TABLE OF CONTENTS

A. Introduction.....	Nuc/Rad Annex-1
A.1 Mission	Nuc/Rad Annex-1
A.2 Purpose	Nuc/Rad Annex-1
A.3 Scope and Applicability	Nuc/Rad Annex-2
A.4 Planning Assumptions	Nuc/Rad Annex-2
A.5 Activation	Nuc/Rad Annex-2
A.6 Supersedence	Nuc/Rad Annex-2
B. Concept of Operations	Nuc/Rad Annex-3
B.1 Emergency Authorities	Nuc/Rad Annex-3
B.2 Emergency Operations Phases	Nuc/Rad Annex-3
B.2.1 Prevention, Protection, and Mitigation	Nuc/Rad Annex-3
B.2.1.1 Surveillance and Detection	Nuc/Rad Annex-4
B.2.1.1.1 Winchester Engineering and Analytical Center	Nuc/Rad Annex-4
B.2.2 Response	Nuc/Rad Annex-4
B.2.2.1 Gain and Maintain Situational Awareness	Nuc/Rad Annex-4
B.2.2.1.1 Alert and Notification	Nuc/Rad Annex-4
B.2.2.1.2 Assessment and Monitoring	Nuc/Rad Annex-4
B.2.2.2 Medical Countermeasures	Nuc/Rad Annex-4
B.2.2.3 Activation and Deployment of Resources and Capabilities	Nuc/Rad Annex-5
B.2.2.4 Coordination of Response Actions	Nuc/Rad Annex-5
B.2.2.4.1 Exposure Determination Information	Nuc/Rad Annex-5
B.2.3 Recovery	Nuc/Rad Annex-6
C. Organization and Assignment of Responsibilities	Nuc/Rad Annex-7
C.1 Office of the Commissioner	Nuc/Rad Annex-7
C.1.1 Office of the Counselor to the Commissioner	Nuc/Rad Annex-7
C.1.1.1 Office of Crisis Management	Nuc/Rad Annex-7
C.1.2 Office of Operations	Nuc/Rad Annex-8
C.1.2.1 Employee Safety and Environmental Management Staff	Nuc/Rad Annex-8
C.1.3 Office of Chief Scientist	Nuc/Rad Annex-8
C.1.3.1 Office of Counterterrorism and Emerging Threats	Nuc/Rad Annex-8
C.2 Office of Foods and Veterinary Medicine	Nuc/Rad Annex-9
C.2.1 Center for Food Safety and Applied Nutrition	Nuc/Rad Annex-9
C.3 Office of Global Regulatory Operations and Policy	Nuc/Rad Annex-10
C.3.1 Office of Regulatory Affairs	Nuc/Rad Annex-10
C.3.1.1 Regional Radiological Health Representatives	Nuc/Rad Annex-10

D.	Direction, Control, and Coordination	Nuc/Rad Annex-11
D.1	Field Incident Command	Nuc/Rad Annex-11
D.2	Headquarters Incident Coordination	Nuc/Rad Annex-11
D.2.1	Command Staff	Nuc/Rad Annex-12
D.2.1.1	Radiological-Specific Liaisons	Nuc/Rad Annex-12
D.2.2	General Staff	Nuc/Rad Annex-12
D.2.2.1	Operations Section	Nuc/Rad Annex-12
D.2.1.2	Drug Group	Nuc/Rad Annex-13
D.2.1.2.1	Expired Drugs Team	Nuc/Rad Annex-13
D.2.1.2.2	Drug Shortage Team	Nuc/Rad Annex-13
D.2.1.2.3	Adverse Drug Events Team	Nuc/Rad Annex-13
D.2.1.3	Biologics Group	Nuc/Rad Annex-13
D.2.1.4	Medical Device Group	Nuc/Rad Annex-13
D.2.1.4.1	In-Vitro Diagnostics Team	Nuc/Rad Annex-13
D.2.1.4.2	Personal Protective Equipment and Other Devices Team	Nuc/Rad Annex-14
D.2.1.4.3	Shortage Team	Nuc/Rad Annex-14
D.2.1.5	Food/Feed Safety Group	Nuc/Rad Annex-14
D.2.2.2	Planning Section	Nuc/Rad Annex-15
D.2.2.2.1	Radiological Emergency Response Unit	Nuc/Rad Annex-15
D.2.2.2.2	Technical Specialists	Nuc/Rad Annex-15
D.2.2.2.3	Employee Health Specialist	Nuc/Rad Annex-15
E.	Communications and Information Management	Nuc/Rad Annex-16
E.1	Emergency Alerts	Nuc/Rad Annex-16
E.2	External Information Sharing	Nuc/Rad Annex-17
E.2.1	Information Sharing Process	Nuc/Rad Annex-17
F.	Authorities and References	Nuc/Rad Annex-19
F.1	Code of Federal Regulations	Nuc/Rad Annex-19
F.2	Federal Plans and Guidance	Nuc/Rad Annex-19
F.3	FDA Supporting Documentation	Nuc/Rad Annex-20
F.3.1	WEAC Radiation Safety Manual	Nuc/Rad Annex-20
F.3.2	CFSAN Radiological Emergency Response Plan	Nuc/Rad Annex-20
F.3.3	FDA Food Protective Guidance	Nuc/Rad Annex-20
Appendix A: Winchester Engineering Analytical Center		Nuc/Rad Annex-21
Appendix B: Activation/Notification of the Advisory Team for Nuclear/Radiological Emergencies		Nuc/Rad Annex-23
Appendix C: Protective Actions		Nuc/Rad Annex-27
Appendix D: Memorandum of Understanding		Nuc/Rad Annex-29
Appendix E: FDA Responsibilities During Radiological Incidents		Nuc/Rad Annex-31



LIST OF FIGURES

Figure D-1. Notional FDA IMG for a Nuclear/Radiological Event	Nuc/Rad Annex-11
Figure D-2. Notional Operations Section Organizational Elements.....	Nuc/Rad Annex-12
Figure E-1. Emergency Alert Reporting Pathways	Nuc/Rad Annex-16
Figure E-2. Notional FDA Food and Agricultural Nuclear/Radiological Incident Communications Links.....	Nuc/Rad Annex-17

LIST OF TABLES

Table A-1. ESF Roles Aligned to Core Capabilities.....	Nuc/Rad Annex-2
Table E-1. FDA Communication Links by IMG Position and Center/Office.....	Nuc/Rad Annex-18
Table C-1. Principal Radionuclides and Corresponding DILs.....	Nuc/Rad Annex-27
Table E-1. FDA Responsibilities for Radiological Incidents.....	Nuc/Rad Annex-31



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A. INTRODUCTION

Radiological emergencies, whether accidental or intentional, have the potential to cause adverse health and safety effects for large segments of the human and animal populations. In order to mitigate the consequences of such incidents, the U.S. Food and Drug Administration (FDA) must possess the resources and capabilities necessary to prevent, prepare for, protect against, and rapidly and effectively respond to and recover from radiological incidents. A planned and coordinated approach to emergency operations by FDA organizational components in support of Federal, State, local, tribal, and territorial (SLTT) governments; international authorities; and responders in the field can save lives and ensure critical public health and medical needs are met.

This *Nuclear/Radiological Annex to the FDA Emergency Operations Plan (EOP)* establishes a framework for FDA's management of radiological incidents. It provides the measures, operating structures, roles and responsibilities, and mechanisms for direction and coordination of FDA resources before, during, and after radiological emergencies that pose a risk to human or animal health. This *Nuclear/Radiological Annex* is compatible with the scalable, flexible, and adaptable Federal Government emergency coordinating structures of the *National Response Framework (NRF)* and is consistent with the concepts, principles, and terminology of the National Incident Management System (NIMS)¹ and the FDA EOP.² This *Nuclear/Radiological Annex* is to be used, in conjunction with the FDA EOP, to assist FDA in conducting response operations for any radiological emergency.

A.1 MISSION

During a radiological emergency, FDA must continue to meet its mission. In addition to the activities listed in the FDA EOP, FDA activities may expand to include performance of specific, incident-related functions such as:

- Activities conducted under the NRF's *Nuclear/Radiological Incident Annex (NRIA)* and *Food and Agriculture Annex*, Emergency Support Functions (ESFs), and the NRF *Catastrophic Incident Supplement*.
- Assistance and recommendations to coordinating agencies and State, tribal, and local governments through the Advisory Team for the Environment, Food, and Health (Advisory Team).³

A.2 PURPOSE

This *Nuclear/Radiological Annex* is intended to be used in conjunction with the FDA EOP and is not intended to be a "standalone" plan. The purpose of the *Nuclear/Radiological Annex* is to detail FDA responsibilities and operations specific to a radiological emergency and provide radiological-specific reference material to provide a coordinated and consistent agency approach to preparing for, preventing, protecting against, responding to, and recovering from radiological incidents involving or impacting FDA-regulated products. To accomplish this, the *Nuclear/Radiological Annex*:

- Is compatible with and expands on the FDA EOP, the overarching FDA-wide operational plan that addresses the full spectrum of natural and technological hazards and terrorist threats and the "umbrella plan" under which the *Nuclear/Radiological Annex* fits.
- Defines the FDA radiological emergency operations structure and assigns essential tasks to the FDA organizational components involved in prevention, protection, response, and recovery efforts.

¹ For more information on the NRF and NIMS, refer to the "Authorities and References" section of this annex and FDA EOP Appendix A and Appendix B or visit www.fema.gov/emergency/nrf/.

² For more information on how the FDA responds to emergencies, refer to the FDA EOP.

³ For more information on the Advisory Team, refer to Appendix B of this *Nuclear/Radiological Annex*.

A.3 SCOPE AND APPLICABILITY

The *Nuclear/Radiological Annex* covers the requirements in anticipation of or in response to a radiological or nuclear incident that affects or involves a FDA-regulated product. This annex applies to both inadvertent and deliberate nuclear/radiological events. According to the NRIA to the NRF, inadvertent releases include: incidents at nuclear facilities (commercial or weapons production facilities), lost radioactive material sources, transportation accidents involving nuclear/radioactive material, domestic nuclear weapons accidents, and foreign accidents involving nuclear or radioactive material that impact the United States or its territories, possessions, or territorial waters, and assistance to other nations and U.S. citizens abroad as requested. In addition, this annex includes, but is not limited to, response to the effects of deliberate attacks perpetrated with radiological dispersal devices (RDDs), nuclear weapons, or improvised nuclear devices (INDs). Refer to FDA EOP Appendix K, “Glossary of Terms” for RDD and IND definitions.

A.4 PLANNING ASSUMPTIONS

The *Nuclear/Radiological Annex* is based on the same planning assumptions as referenced in the FDA EOP and, in addition:

- The U.S. Department of Homeland Security (DHS) will review the situation and determine whether to assume Federal leadership for the overall response in accordance with the NRF.
- To ensure the capability to implement the *Nuclear/Radiological Annex*, each FDA headquarters and field organizational component tasked with radiological emergency roles and responsibilities, as identified in this *Nuclear/Radiological Annex* or the FDA EOP, may develop and maintain individual emergency plans and procedures that identify the critical and time-sensitive missions, functions, assignments, and processes to be performed by their organizational component during a radiological incident. These documents shall be consistent with the FDA EOP and this annex and available to all Center/Office personnel.

A.5 ACTIVATION

The ESF #8 – Public Health and Medical Services response to a radiological event will be directed by the U.S. Department of Health and Human Services (HHS) Office of the Secretary, in coordination with DHS, which is responsible for managing the U.S. Government response. FDA is a subordinate Operating Division (OPDIV) of HHS and will align its response activities with those of HHS. FDA will use the full spectrum of its resources to accomplish assigned roles, responsibilities, functions, goals, and missions.

This annex will be consulted and implemented together with the FDA EOP when there is a radiological incident. Examples of events that could trigger activation of this annex include, but are not limited to, any radiological incident, including nuclear power plant accidents, manmade accidents, RDDs, or INDs. Such events may impact FDA-regulated products/industries, lead to a response from FDA via the Advisory Team, or result in the request for the issuance/use of Emergency Use Authorizations (EUAs) or emergency use Investigational New Drugs (INDs) for a medical countermeasure.

Regional Food and Drug Directors (RFDDs), District Directors (DDs), and Center/Office Directors may activate their individual organizational component’s EOP without activation of the FDA *Nuclear/Radiological Annex*.

A.6 SUPERSEDEANCE

This *Nuclear/Radiological Annex to the FDA EOP* (2014) supersedes the FDA EOP *Nuclear/Radiological Annex* (2010).

B. CONCEPT OF OPERATIONS

The following concept of operations (CONOPS) describes the principal authorities' governing agency emergency functions and the phases within which FDA conducts radiological incident-related operations.

B.1 EMERGENCY AUTHORITIES

FDA's emergency authorities are prescribed by several statutes and conducted in accordance with applicable regulations as described in FDA EOP *Section F*, "Authorities and References." These include the Pandemic and All-Hazards Preparedness Reauthorization Act (Public Law 113-5) and Title 21, "Food and Drugs," of the Code of Federal Regulations (CFR).⁴ In addition to the authorities listed in the FDA EOP, the emergency authority relevant to a radiological/nuclear incident is:

- Title 44, "Emergency Management and Assistance," CFR Part 351 "Radiological Emergency Planning and Preparedness," authorizes FDA to assist State and local government officials in preparing for radiological emergencies and in the development of their radiological plans.

B.2 EMERGENCY OPERATIONS PHASES

The following phases comprise the entire spectrum of FDA emergency operations: ***Prevention, Protection, Mitigation, Response, and Recovery***. During a nuclear/radiological event FDA employees are expected to follow the activities described in the FDA EOP, *Section B.2*, "Emergency Operations Phases." Although emergency operations may involve each of these phases over the course of a radiological incident, the nature and severity of an event and the FDA organizational component(s) responding will determine the specific order, actions, and responsible parties required for each.⁵ The following sections describe additional resources available during FDA's emergency operations for prevention and protection specific to a radiological or nuclear event.

B.2.1 Prevention, Protection, and Mitigation

FDA participates in a number of planning subcommittees under the Federal Radiological Preparedness Coordinating Committee (FRPCC), which coordinates all Federal responsibilities for assisting State and local governments in their emergency planning and preparedness for peacetime radiological emergencies, developing protective action recommendations (PARs) for human and animal feed, providing guidance on radioprotective substances and prophylactic drugs to reduce radiation dose, and providing medical and mental health support through ESF #8. The Federal Emergency Management Agency (FEMA) is the chair of the FRPCC, and FDA serves as the chair of the FRPCC Subcommittee on Food, Health, and Environment.

The FRPCC performs the following functions:

- Assisting the FEMA Director in providing policy direction with respect to Federal assistance to State and local governments in their radiological emergency planning and preparedness activities.
- Establishing subcommittees to aid in carrying out its functions; current subcommittees include Training, Offsite Instrumentation, Transportation, and Federal Response.
- Assisting FEMA in resolving issues relating to granting final approval (under 44 CFR Part 350) of a State radiological emergency preparedness plan.

⁴ A more detailed summary of the laws, regulations, directives, and policy guiding FDA emergency operations is provided in Section F, "Authorities and References," of this annex and the FDA EOP.

⁵ Refer to Section C, "Organization and Assignment of Responsibilities," of this annex for an overview of FDA organizational component roles and responsibilities during a radiological incident.

- Coordinating research and study efforts of its member agencies relative to State and local government radiological emergency preparedness to ensure minimum duplication and maximum benefits to State and local governments.

The FRPCC works directly with HHS, the Centers for Disease Control and Prevention (CDC), and FDA seeking guidance for State and local governments on the use of radioprotective substances and prophylactic use of drugs (e.g., potassium iodide, Radiogardase®) to reduce the radiation dose to specific organs, including dosage and projected radiation exposures.

B.2.1.1 Surveillance and Detection

B.2.1.1.1 Winchester Engineering and Analytical Center

Winchester Engineering and Analytical Center (WEAC) is an FDA/Office of Regulatory Affairs (ORA) laboratory that is equipped and staffed to handle the analysis of radioactive materials. It is the Federal laboratory having the greatest capability in the United States to analyze food samples for radioactive contamination. As such, WEAC serves as the lead for the radiological component of the Food Emergency Response Network (FERN).⁶ The FDA FERN program is administered by the ORA Division of Regulatory Science. FDA conducts import and domestic food surveillance programs for radioactive contamination (e.g., import samples, onsite authorities or SLTT investigator-provided samples, market basket survey samples).

B.2.2 Response

B.2.2.1 Gain and Maintain Situational Awareness

B.2.2.1.1 Alert and Notification

FDA may be alerted to a threat, hazard, or other significant event through a variety of means, including the surveillance systems discussed in the FDA EOP Table B-1 (Surveillance and Detection Systems Utilized by FDA) and/or directly from external Federal Agencies (e.g., the HHS Secretary's Operations Center [SOC], U.S. Environmental Protection Agency [EPA], DHS, U.S. Department of Energy [DOE], U.S. Nuclear Regulatory Commission [NRC], and/or the Federal Bureau of Investigation [FBI]); SLTT and international public health agencies; industry; consumers; news media; and internal FDA organizational components.

If FDA becomes aware of a radiological incident from a non-DHS agency, it should notify the coordinating agency and the DHS National Operations Center (NOC) at **202-282-8101** and comply with other appropriate statutory requirements for notification. If FDA becomes aware of an overt threat or act involving nuclear/radiological material/device or indications the event is not inadvertent or otherwise accidental, the U.S. Department of Justice (DOJ) should be notified through the FBI.

B.2.2.1.2 Assessment and Monitoring

During a radiological response, WEAC is the lead FDA laboratory for the analysis of radionuclides in foods, drugs, and medical devices for radiological emergency consequence management.

B.2.2.2 Medical Countermeasures

Information on available medical countermeasures and evaluation of EUAs can be provided by the Office of Counterterrorism and Emerging Threats (OCET) or Center emergency coordinators, as needed, through their contact and work with Center subject matter experts (SMEs).

⁶ For more information on the radiological FERN and WEAC, refer to Appendix A of this *Nuclear/Radiological Annex*.

B.2.2.3 Activation and Deployment of Resources and Capabilities

FDA is a member and currently the chair of the Advisory Team, a Federal interagency group of radiation SMEs who provide coordinated, science-based advice and recommendations to the coordinating agency⁷ and/or the State, tribal, and local government on protective measures that may be taken following a radiological incident. The Advisory Team comprises representatives from the EPA, U.S. Department of Agriculture (USDA), and HHS, including the CDC and FDA. Other departments or agencies may be asked to participate as needed. The Advisory Team works closely with the Federal Radiological Monitoring and Assessment Center (FRMAC), an interagency group led by the DOE National Nuclear Security Agency (NNSA).⁸

If Federal assistance is requested for a radiological/nuclear incident and Advisory Team participation is needed, FDA will send an ORA Regional Radiological Health Representative(s) (RRHR) to the Unified Command (UC) as part of the onsite Advisory Team. (See **Appendix B** for activation/notification procedures of the Advisory Team.) Other Advisory Team members will be available at headquarters or in other locations to provide reachback and coverage when the remote Advisory Team member(s) is in transit or otherwise unavailable.

B.2.2.4 Coordination of Response Actions

During the response phase, FDA's role is to provide information about countermeasures and facilitate their availability as stated in the FDA EOP, *Section B.2.2.3.5*, "Medical Countermeasures: EUA and Expanded Access." Through the Advisory Team, FDA provides guidance to State and local agencies on interdicting suspected food from the food supply, as well as support for making protective action decisions.

To assist FDA's Emergency Operations Center (EOC) in responding to a radiological emergency, staff personnel in the medical product Centers maintain the status of medical countermeasure product availability and relevant manufacturing information. Each Center has detailed policies and procedures in place to make critical medical countermeasures available, and the FDA EOC coordinates the sharing of this information during an emergency.

B.2.2.4.1 Exposure Determination Information

Based on data provided by FRMAC and other field organizations, the coordinating agency will provide the following information, which may be helpful in guiding decisions about medical countermeasures or other protective actions:

- Identity of the radioisotopes.
- Quality of radiation (alpha, beta, gamma, and neutrons).
- Nature of the incident (e.g., nuclear power plant release, IND or RDD).
- Casualty information, including estimates of combined radiation and non-radiation injuries, such as blast and burn.

⁷ Coordinating agencies are those Federal Agencies that own, have custody of, authorize, regulate, or are otherwise assigned responsibilities for the nuclear/radioactive material, facility, or activity involved in the incident. A listing of coordinating agencies can be found in Table 1 of the NRF NRIA.

www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf

⁸ For additional information, see the NRF NIRA.



- Plume direction and characteristics (estimated population exposure), including Shape files, which can be used to generate geographic information system (GIS) maps for situational awareness and planning.
- Amount of external radiation exposure.

This information may assist coordinating agencies in predicting who may develop:

- Hematopoietic syndrome (projected needs for cytokines and antimicrobials).
- Gastrointestinal syndrome (possible use of investigational cytokines).
- Cardiac/central nervous system syndrome (following extremely high doses, with death likely).

B.2.3 Recovery

During the recovery phase, some FDA objectives that would support Federal or SLTT agencies are:

- To manage a potentially large number of samples of FDA-regulated products associated with nuclear/radiological releases, including long-term (months to years) sampling, product destructions, and product reconditioning, as applicable.
- To provide technical support to the Advisory Team in establishing “clean-up” levels in following a radiological incident.

C. ORGANIZATION AND ASSIGNMENT OF RESPONSIBILITIES

This section identifies the roles and responsibilities specific to a radiological incident of FDA headquarters and field organizational components in preventing and protecting against, responding to, and recovering from a radiological incident. FDA staffs work closely with one another and with governmental and industry partners to ensure the safety, efficacy, and security of FDA-regulated products that mitigate the public health effects of an emergency or disaster in the United States or worldwide. This is done by using novel and expeditious approaches to product regulation in order to optimize the availability and use of FDA-regulated products in all populations.

The following is a brief description of the radiological emergency functions performed by responsible organizational components.⁹ Refer to individual Center/Office emergency plans and procedural documentation, as applicable, for more detailed information on radiological emergency activities. For additional information on general FDA Center/Office emergency roles and responsibilities, refer to the FDA EOP, *Section C*, “Organization and Assignment of Responsibilities.”

FDA product Centers are responsible for the regulation of a defined set of products. Their professional staff includes both clinical and scientific experts. This expertise (i.e., analytical, laboratory, sampling procedures, subject matter expertise, and industry knowledge) is available for critical consultation in the event of a nuclear/radiological incident. In addition, the Center for Food Safety and Applied Nutrition (CFSAN) has responsibilities that are specific to a radiological incident.¹⁰

C.1 OFFICE OF THE COMMISSIONER

C.1.1 *Office of the Counselor to the Commissioner*

C.1.1.1 Office of Crisis Management

In addition to the activities specified in the FDA EOP, the Office of Crisis Management (OCM) and Office of Emergency Operations (OEO) will communicate with external coordinating agencies and share information with internal FDA entities for nuclear/radiological incidents affecting FDA-regulated products. Dependent on the type of incident, some of the agencies with which FDA would communicate are: the U.S. Department of Defense (DoD), DOE, National Aeronautics and Space Administration (NASA), DHS, EPA, and the NRC. For a detailed description of what the NRF provides about the response and coordinating responsibilities, see the NRF NRIA at www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf.

⁹ Those FDA organizational components without defined radiological emergency roles or responsibilities are not described within this annex.

¹⁰ Responsibilities of CFSAN are described in Appendix W, “CFSAN Radiological Emergency Response Plan” of the *CFSAN Emergency Response Plan*, March 2011.



The external coordinating agencies will share with OCM/OEO (EOC) information about response activities of interest to FDA. The information to be shared with FDA includes but is not limited to:

Response Activities Information	Responsible Federal Agency
Laboratory Analysis	CDC, EPA, and/or DOE
Atmospheric Plume Modeling Data	Interagency Modeling and Atmospheric Center (IMAAC)/National Atmospheric Release Advisory Center (NARAC), DHS, and/or DOE/Lawrence Livermore National Laboratory
Population Modeling Data	HHS (ESF #8) or DHS
PARs	Advisory Team
Contaminated Animal Management	USDA (ESF #3 and ESF #10)

Source: NRF NRIA Table 4, "Nuclear/Radiological Incident Response Activities." For a description of the responsible Federal Agencies, see www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf.

OCM/OEO will also be responsible for alert and notification of the Advisory Team in response to activation or consultation requests from Federal Agencies and/or SLTTs. OCM/OEO will support Advisory Team operations by providing conference call support and interface with the FDA Incident Management Group (IMG), when activated.

C.1.2 Office of Operations

C.1.2.1 Employee Safety and Environmental Management Staff

The Employee Safety and Environmental Management Staff (ESEMS) provides agency-wide occupational safety, occupational medicine, and environmental management oversight for all FDA activities, including the FDA Radiation Safety Program. Through coordination with FDA Centers and Offices, the ESEMS ensures the mission of the FDA is achieved with the necessary focus on employee safety and environmental stewardship. The ESEMS oversees the occupational medicine program nationwide and provides oversight of the FDA Radiation Safety Committee. ESEMS members serve as lead for the Radiological Emergency Response Unit and as chair of the Advisory Team.

C.1.3 Office of Chief Scientist

C.1.3.1 Office of Counterterrorism and Emerging Threats

OCET works with FDA's medical product Centers to ensure the availability of medical countermeasures that can improve survival and mitigate and treat injuries from radiological/nuclear events and their delayed effects including acute radiation syndrome. These include decorporation or blocking agents to reduce internal contamination from exposure to radionuclides and biodosimetry devices that can be used in a radiological/nuclear event to assess exposure to radiation and facilitate response activities.

C.2 OFFICE OF FOODS AND VETERINARY MEDICINE

C.2.1 Center for Food Safety and Applied Nutrition

CFSAN, in conjunction with the agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the Nation's food supply is safe, sanitary, wholesome, and honestly labeled and that cosmetic products are safe and labeled properly. In addition to the activities described in the FDA EOP, CFSAN is responsible for, but not limited to, the following activities during radiological emergency:

- Oversees the safety of the U.S. food supply following radiological emergencies through its Compliance Program and its participation with the Advisory Team, using the FDA food protective action guidance as the principal source of doctrine.
- Through its involvement with FRMAC, participates in the development of assessment methods and guidance for food protective measures.
- Provides scientific, technical, and policy expertise, guidance, and support within FDA and to other Federal and State agency components, regulated industry, and the public.
- Issues recommendations and guidelines on acceptable levels of radioactive contamination of foods, dietary supplements, and cosmetics.
- Provides advice regarding health risks from radioactive contamination of food, dietary supplements, and cosmetics; this includes advice on actions that can be taken by FDA, State and local authorities, industry, or consumers to reduce public exposure to contaminated food, dietary supplements, and cosmetics.
- Oversees the overall response to verify that the necessary food- and cosmetic-related actions are taken.
- Provides advice regarding sampling procedures and testing methodology (screening and confirmatory).
- Provides advice regarding product traceback and traceforward investigations.
- Develops field programs to meet intermediate to long-range consequence management needs.

C.3 OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

C.3.1 Office of Regulatory Affairs

ORA, led by the Associate Commissioner for Regulatory Affairs (ACRA), protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products. ORA is the lead office for all agency field activities. In addition to the activities described in FDA EOP, ORA is responsible for providing RRHRs and other qualified ORA staff, as needed, to be FDA representatives to the field component of the Advisory Team.

C.3.1.1 Regional Radiological Health Representatives¹¹

The RRHRs represent the agency on committees chaired by FEMA that include representatives from the U.S. Public Health Service (USPHS), EPA, USDA, NRC, U.S. Coast Guard (USCG), and others. These committees are responsible for evaluating State and local emergency plans for nuclear power plants and radiological emergencies.

In addition to serving as representatives on these committees, the RRHRs represent FDA on the onsite Advisory Team (Section B.2.2.3) during a radiological incident. Other FDA SMEs may also represent FDA on the Advisory Team through deployment, or via telephone/email in a reachback status. FDA staff is activated for the Advisory Team as per the Advisory Team Activation Standard Operating Procedure (SOP) (see **Appendix B**). When an incident has occurred, RRHRs are the agency's onsite representatives to the Advisory Team. If there is a request for PARs for FDA-regulated products, RRHRs help develop the recommendations, in consultation with other FDA scientific and policy experts. For additional information on PARs and Protective Action Guides (PAGs), refer to **Appendix C**, "Protective Actions."

¹¹ The duties and responsibilities of the RRHRs are defined in *Compliance Program Guidance Manual (CPGM)* Program No. 7386.009, "Emergency Planning and Response Activities."

D. DIRECTION, CONTROL, AND COORDINATION

This section provides a description of radiological-specific positions and teams and describes their primary roles and responsibilities. These individuals are expected to have read and be familiar with the NRF NRIA (see www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf).

FDA organizes emergency response operations in accordance with the concepts, principles, and terminology of the Incident Command System (ICS), as defined within NIMS.¹² Incident Command and subordinate Planning, Operations, Logistics, and Finance/Administration functions lay the foundation for the agency's implementation of ICS during all hazards, at headquarters and field levels, and across geographic divides. The inherent design of this system enables rapid, scalable, and flexible agency-wide emergency management activities.

D.1 FIELD INCIDENT COMMAND

FDA field response will be established as described in FDA EOP, *Section B.2.2.3.2*, "FDA Field Response" and *Section D.1*, "Field Incident Command." Depending on the location of the incident and extent of potential contamination, an Incident Management Team (IMT) may be established. The IMT will coordinate with IMG, Advisory Team, and SLTT agencies to respond to an incident. FDA does not have a role in collecting data in restricted areas with high levels of radiological contamination.

D.2 HEADQUARTERS INCIDENT COORDINATION

As FDA's coordination point for emergencies, due to the severity or potential consequences of a nuclear/radiological incident, an IMG will be established to address the public health impact. **Figure D-1** depicts a notional IMG emergency response coordinating structure for a radiological incident.

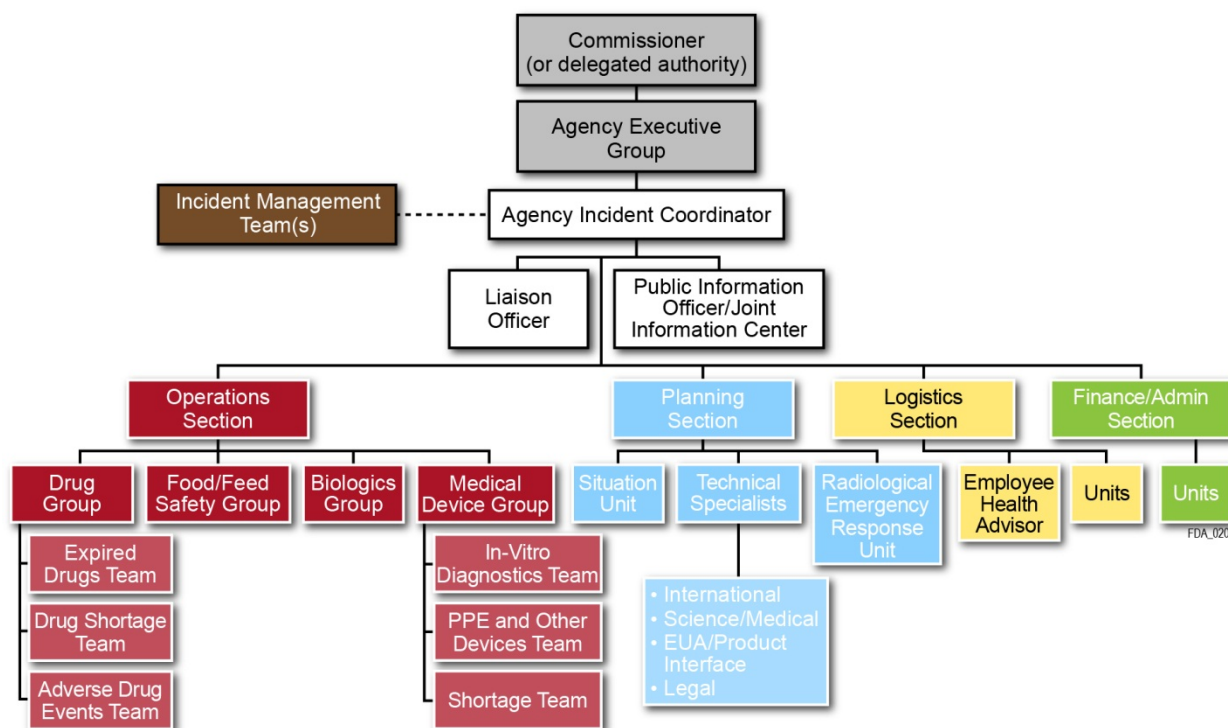


Figure D-1. Notional FDA IMG for a Nuclear/Radiological Event

¹² For more information on the ICS, refer to www.training.fema.gov/EMIWeb/IS/ICSResource/index.htm.

D.2.1 Command Staff

The FDA Command Staff includes a Public Information Officer (PIO), Liaison Officers (LNOs), and a Legal Specialist.

D.2.1.1 Radiological-Specific Liaisons

When activated, the FDA EOC serves as the agency-wide focal point for radiological emergency operations, coordination, and communications for incidents involving regulated products. External liaisons from the USDA, NRC, or other agencies may be present at the FDA EOC. FDA may also send liaisons to the coordinating agency for the incident, or participate in the response coordination, if an Incident Command or UC is established.

D.2.2 General Staff

The General Staff is responsible for the functional aspects of the FDA ICS. The General Staff consists of Operations, Planning, Logistics, and Finance/Administration Sections composed of designated FDA headquarters and field emergency staff. Individual position assignments within these Sections are outlined in the FDA EOP.

D.2.2.1 Operations Section

The Operations Section is responsible for coordinating all agency field activities in response to a radiological/nuclear event involving a regulated product. **Figure D-2** depicts FDA's Operations Section during the event. The groups included in the chart below could possibly be established when the number of resources exceeds the manageable span of control of the IMG and Operations Section Chief. Groups are established to divide the incident into functional areas of operation. Additional levels of supervision may also exist below the group level.

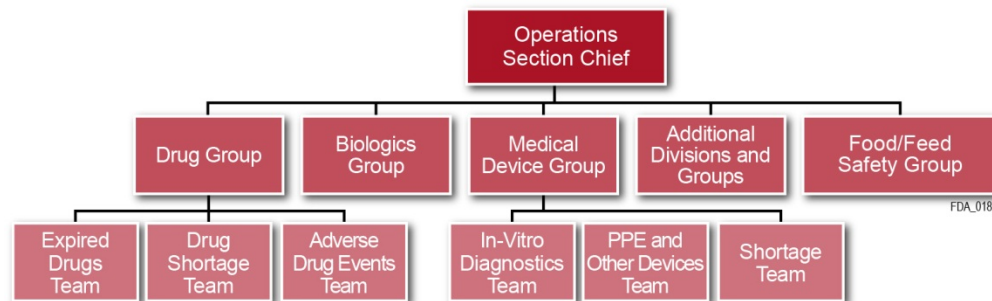


Figure D-2. Notional Operations Section Organizational Elements

Expansion or contraction of the Operations Section may vary according to numerous considerations and operational factors associated with an incident. In some cases, a functional approach may be used. In other cases, the organizational structure will be determined by geographical or Center/Office jurisdictional boundaries. In still others, a mix of functional and geographical considerations may be appropriate. The Agency Incident Coordinator (AIC) will determine the appropriate structural approach based on the specific circumstances of the incident at-hand.

D.2.1.2 Drug Group

The Drug Group addresses drug issues such as adverse event reporting, labeling changes, whether EUAs for drugs are appropriate, and what restrictions should be placed on uses authorized under EUAs related to a radiological operational response. Some potential teams, led by Center for Drug Evaluation and Research (CDER) staff, which may be needed to manage mitigation and recovery issues include:

- Expired Drugs Team
- Drug Shortage Team
- Adverse Drug Events Team

D.2.1.2.1 Expired Drugs Team

The Expired Drugs Team deals with such issues as use of expired drugs and drugs out of specification, including those in the Strategic National Stockpile (SNS). This team would have input in discussing whether an EUA should/can include private sector stockpiles (e.g., hospital associations, large employers) or whether a separate authorization is needed. The Expired Drugs Team would also monitor labeling and Shelf Life Extension Program (SLEP) issues related to the event.

D.2.1.2.2 Drug Shortage Team

The Drug Shortage Team is responsible for reporting on the availability and surge capacity for drugs, monitoring commercial inventory, and working with manufacturers of drug products to prepare for possible increases in demand. The team would contact intravenous fluid manufacturers and other critical care drug manufacturers to prepare for possible increased needs.

D.2.1.2.3 Adverse Drug Events Team

The Adverse Drug Events Team assists with the monitoring of adverse drug events to identify undesired side effects and unexpected adverse effects from a drug product used for treatment.

D.2.1.3 Biologics Group

The Biologics Group addresses blood and other biologics issues as part of a radiological/nuclear operational response.

D.2.1.4 Medical Device Group

The Medical Device Group would manage issues related to a radiological/nuclear operational response. Potential teams, with leaders from Center for Devices and Radiological Health (CDRH) staff members, who may be needed to manage mitigation and recovery issues, are:

- In-Vitro Diagnostics (IVD) Team
- Personal Protective Equipment (PPE) and Other Devices Team
- Shortage Team

D.2.1.4.1 In-Vitro Diagnostics Team

The IVD Team addresses issues related to the following:

- Triage of EUA requests.
- Response to inquiries regarding EUA requests from the CDC, DoD, and domestic and international commercial sources for IVDs claiming to assess radiation exposure.
- Contact with manufacturers regarding assays and instruments to be used in development of IVDs.

- Clear or approved tests and instruments that detect and measure in situ radioisotope contamination and absorbed radiation dose in exposed individuals.
- Monitor reagent and system shortages on a short-term daily or weekly basis as well as a long-term monthly basis.
- Monitor radiation biodosimetry and in situ radioactivity contamination detection device functional claims.
- Review data and labeling of cleared or approved devices for which a company is proposing new claims and changes.
- Address fraudulent claims by monitoring websites and complaints regarding product claims and issue warning letters as appropriate.

D.2.1.4.2 Personal Protective Equipment and Other Devices Team

The PPE and Other Devices Team oversee or manage the following:

- Exchange of information with the CDC/SNS, States, and manufacturing sector and real-time monitoring of consumption/utilization rates of PPE during emergencies.
- Respond to State and private sector inquiries about perceived shortages during public health emergencies.
- Anticipate and plan for future surges in demand for devices.
- Track/trace status of devices released from SNS.
- Meet with manufactures about the development of new PPE.
- Address PPE shortages by working with industry to update current manufacturing capabilities and assist with long-term planning by the manufacturing sector to meet demands for potential surges.

D.2.1.4.3 Shortage Team

The Shortage Team would be created if shortages of IVD, PPE, and other devices are too extensive to be managed by the above teams alone.

D.2.1.5 Food/Feed Safety Group

The Food/Feed Safety Group addresses issues related to the following:

- Providing scientific, technical, and policy expertise, guidance, and support within FDA and to other Federal and State agency components, regulated industry, and the public.
- Providing advice regarding health risks from radioactive contamination of food and cosmetics and advice on actions that can be taken by FDA, State and local authorities, industry, or consumers to reduce public exposure to radiation.
- Evaluating and providing guidance for food- and cosmetic-related response actions.
- Advice regarding sampling plan and procedures and testing method (screening and confirmatory).
- Advice regarding product traceback and traceforward investigations.
- Developing field programs to meet intermediate to long-range consequence management needs.



D.2.2.2 Planning Section

The Planning Section is responsible for collecting, evaluating, and disseminating operational information pertaining to the incident. This Section maintains information and intelligence on the current and forecasted situation, as well as the status of FDA resources assigned to the incident. Technical Specialists may be assigned to the Planning Section or to other IMG Sections as determined by the AIC.

D.2.2.2.1 Radiological Emergency Response Unit

The Radiological Emergency Response Unit is comprised of a cadre of radiological health experts from relevant Centers/Offices with a variety of backgrounds, including health physics, medical physics, radiology, nuclear medicine, and radiation oncology. The unit provides technical advice to FDA senior management and liaisons to external agencies. The Unit Leader is identified by OCM in coordination with the FDA representative on the Advisory Team.

D.2.2.2.2 Technical Specialists

Technical Specialists such as Science/Medical Specialists and EUA/Product Interface Specialists are normally assigned to the Planning Section, but may support any ICS function including the Command Staff at the discretion of the AIC.¹³

D.2.2.2.3 Employee Health Specialist

The Employee Health Specialist is a staff member of OCET or the Office of Operations (OO)/ESEMS who addresses the need for appropriate health protection for high-risk FDA employees. The Employee Health Specialist works with HHS and the USPHS Federal Occupational Health (FOH) Services to ensure adequate medical countermeasures are made available to protect FDA responders. The Employee Health Specialist is assigned to the Planning Section or can be called to serve in the Logistics Section.

¹³ See FDA EOP, Section D, “Direction, Control, and Coordination” for a description of the Technical Specialist positions.

E. COMMUNICATIONS AND INFORMATION MANAGEMENT

Effective emergency management and incident response activities rely upon flexible communications and information systems that provide for a “common operating picture” across all agency components and staffs. Radiological/nuclear incident responders are expected to follow the FDA EOP, *Section E*, “Communications and Information Management.”

E.1 EMERGENCY ALERTS

FDA may receive alert and notification of a domestic nuclear/radiological incident from multiple external agencies. These notifications in the process may occur simultaneously following detection of an incident (see **Figure E-1**). Possible reporting pathways include alerts from:

- A. FRMAC to the Advisory Team through the FDA EOC (see **Appendix B**). Because of existing protocols outlined in the NRIA-NRF, the FRMAC may initially contact the CDC Director’s Emergency Operations Center (DEOC), who will contact the FDA EOC for notification of the Advisory Team.
- B. State or local government representative(s) to the Advisory Team through the FDA EOC. Because of existing protocols outlined in the NRIA-NRF, State and local government officials may initially contact the CDC DEOC, who will contact the FDA EOC for notification of the Advisory Team.
- C. NRC to the Advisory Team through the FDA EOC.
- D. NRC to FEMA to the HHS SOC to the FDA EOC.

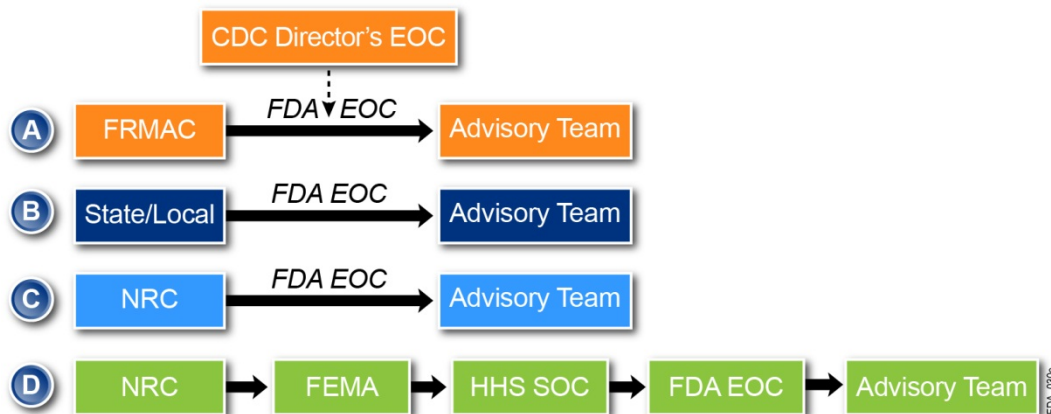


Figure E-1. Emergency Alert Reporting Pathways

Any FDA element alerted to an incident should promptly report the information to the FDA EOC.

Upon receipt, OCM/OEO emergency coordinators or Late Duty Officer (LDO) will use contact information contained in the “Advisory Team” tab of the OCM/OEO Redbook to make the appropriate notifications.

E.2 EXTERNAL INFORMATION SHARING

Pre-identified communication pathways and information sharing methods must be established among agencies and organizations responsible for responding to a radiological incident. Effective and systematic information sharing will enhance response coordination and public messaging. FDA Centers/Offices are responsible for obtaining and updating their respective external agencies' contact information.

E.2.1 Information Sharing Process

This section identifies specific external agencies that FDA links to for information exchange and dissemination. Not all Centers/Offices will or should be communicating with partner or external agencies. This annex specifically defines the primary FDA point of contact (POC) for each external agency or industry partner. The primary links when an IMG is activated are summarized in **Figure E-2** and **Table E-1**.

Figure E-2 shows the primary communications links established by the IMG and its Radiological Emergency Response Unit with external agencies during a response. (An example of a full nationalized IMG organization is shown in **Figure D-1**.) The Radiological Emergency Response Unit is comprised of radiological experts who provide technical advice and serve as representatives to external agencies. Agencies external to FDA are shown in orange.

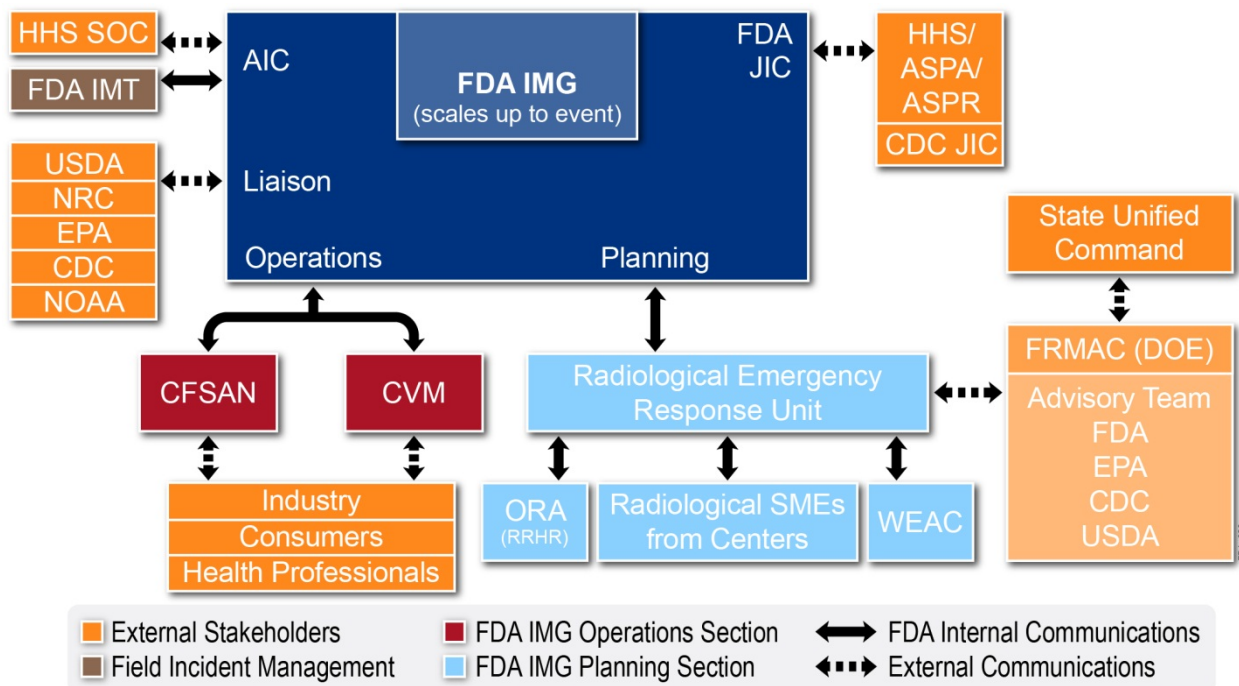


Figure E-2. Notional FDA Food and Agricultural Nuclear/Radiological Incident Communications Links

Table E-1 expands upon the communication links shown in **Figure E-2** for a food and agricultural nuclear incident response and provides a summary of responsibilities for external communications. FDA roles are listed by IMG position and the supporting Center/Office. For each position, the chart lists the primary external POCs. Communication modes can include telephone, email, situation reports, inter-agency teleconferences, and 50-State teleconferences.

Table E-1. FDA Communication Links by IMG Position and Center/Office

IMG Position	Center/Office	External POCs	Notes
Command Staff			
AIC	OCM	HHS SOC/ESF #8	
IMG PIO/FDA Joint Information Center (JIC)	<ul style="list-style-type: none">Office of External Affairs (OEA)CFSAN	HHS Assistant Secretary for Preparedness and Response (ASPR) and Assistant Secretary for Public Affairs (ASPA)	
		Media	
		<ul style="list-style-type: none">ConsumersIndustryHealth Professionals	
		<ul style="list-style-type: none">National Incident Communications Conference Line (NICCL)State Incident Communications Conference Line (SICCL)Private Sector Incident Communications Conference Line (PICCL)	Monitor calls
		<ul style="list-style-type: none">USDA (Office of the Secretary Communications and others)CDC JIC	
		Incoming consumer calls	JIC provides information out to Centers to respond
LNO		<ul style="list-style-type: none">USDANRCEPACDCNational Oceanic and Atmospheric Administration (NOAA)	
General Staff			
Operations Section			
Food and Feed Safety Group	<ul style="list-style-type: none">CFSANCenter for Veterinary Medicine (CVM)ORA Office of Food and Feed Operations (OFFO)ORA Office of Partnerships (OP)	<ul style="list-style-type: none">State UCFRMACAdvisory Team	Supports Advisory Team in reachback status
		<ul style="list-style-type: none">ConsumersIndustryHealth Professionals	In coordination with JIC
		Food and Agriculture Cross Sector	<ul style="list-style-type: none">Sector and consumer calls in coordination with the JICAlso participate in Nuclear Reactors, Materials and Waste Sector call
		States	50-State call in coordination with JIC
Planning Section			
Radiological Emergency Response Unit	<ul style="list-style-type: none">OOORA RRHRMultiple Center/Office SMEsFERNWEAC	<ul style="list-style-type: none">State UCFRMACAdvisory Team	Supports Advisory Team in reachback status
International Specialist	Office of International Programs (OIP)	HHS Office of Global Affairs	Add as needed
Logistics Section			
Employee Health Specialist	<ul style="list-style-type: none">OOOCET	<ul style="list-style-type: none">HHSUSPHS	USPHS FOH Services

F. AUTHORITIES AND REFERENCES

The legal authorities that guide the structure, development, and implementation of this *Nuclear/Radiological Annex* include statutes and regulations, Presidential directives, national strategies, and Federal Government plans and guidance. In addition, internal emergency plans and procedures augment the *Nuclear/Radiological Annex* and provide specific guidance to agency personnel during emergencies and disasters. In addition to the authorities and references listed in the FDA EOP, *Section F*, “Authorities and References,” the following authorities and references apply.¹⁴

F.1 CODE OF FEDERAL REGULATIONS

Title 44 CFR Part 351, “Radiological Emergency Planning and Preparedness,” authorizes Federal Agencies, including HHS, to assist State and local government officials in the development of their radiological plans (see www.access.gpo.gov/nara/cfr/waisidx_02/44cfrv1_02.html).

F.2 FEDERAL PLANS AND GUIDANCE

The following list of Federal plans and guidance are applicable during a nuclear/radiological event. For a more detailed description, please see the following links:

- ESF #8 – Public Health and Medical Services
<http://www.fema.gov/media-library/assets/documents/32198?id=7359>
- ESF #10 – Oil and Hazardous Materials Response
www.fema.gov/media-library/assets/documents/32241?id=7376
- ESF #11 – Agriculture and Natural Resources
www.fema.gov/media-library/assets/documents/32213?id=7365
- Food and Agriculture Incident Annex
www.fema.gov/media-library/assets/documents/25552?fromSearch=fromsearch&id=5527
- National Oil and Hazardous Substances Pollution Contingency Plan
www.epa.gov/OEM/content/lawsregs/ncpover.htm
- NRF NRIA
www.fema.gov/media-library/assets/documents/25554?fromSearch=fromsearch&id=5528
- Terrorism Incident Law Enforcement and Investigation Annex
www.learningservices.us/pdf/emergency/nrf/nrp_terrorismincidentlawenforcementannex.pdf

¹⁴ This list is not exhaustive, and the associated summaries should not be used as a substitute for the authorities and references themselves.



F.3 FDA SUPPORTING DOCUMENTATION

F.3.1 WEAC Radiation Safety Manual

Radiation Safety Manual, *Winchester Engineering and Analytical Center Policies and Procedures for Users of Radioactive Material and Radiation Emitting Devices*, issued by the WEAC Radiation Committee.

F.3.2 CFSAN Radiological Emergency Response Plan

The CFSAN Radiological Emergency Response Plan describes the responsibilities and actions to be taken by CFSAN in response to a radiological emergency. The document is Appendix W, “CFSAN Radiological Emergency Response Plan” to the *CFSAN Emergency Response Plan*.

F.3.3 FDA Food Protective Guidance

FDA has guidance on acceptable levels of radioactive contamination in food (called Derived Intervention Levels [DILs]) entitled, *Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies* (CDRH, 1998). This guidance provides a method for calculating the DIL for a specific radionuclide based on a limiting radiation dose to an individual consuming food contaminated at the level of a DIL for a period of 1 year. This guidance has been adopted by many States for their nuclear power plant safety programs and has been incorporated into EPA’s PAG Manual. FDA’s representatives on the Advisory Team, along with CFSAN radiation SMEs, assist with the interpretation of the guidance.

APPENDIX A: WINCHESTER ENGINEERING ANALYTICAL CENTER

FERN – Radiological

FDA's WEAC radiological laboratory has analytical sample capacity during 24 hours a day, 7 days a week (24/7) operation of several hundred gamma-ray analyses per day and tens of beta- or alpha-particle analyses per week. The FERN radiological laboratories are activated by the WEAC Center Director and the FERN National Program Office when analytical surge capacity is required.

FERN will integrate the Nation's food-testing laboratories at the local, State, and Federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. FERN, shared between USDA/Food Safety and Inspection Service (FSIS) and HHS/FDA, is organized to ensure ongoing Federal and State interagency participation and cooperation in the formation, development, and operation of the network (www.fernlab.org).

FERN plays a number of critical roles related to food security and food defense. These include:

- **Prevention.** FERN provides a national surveillance program that will offer early means of detecting threat agents in the American food supply.
- **Preparedness.** FERN prepares the Nation's laboratories to be able to respond to food-related emergencies.
- **Response.** FERN offers significant surge capacity that will strengthen the Nation's response toward widespread complex emergencies and international or inadvertent related agents in foods.
- **Recovery.** The FERN network of laboratories will enhance the ability of the country to restore confidence in the food supply following a threat or an actual emergency.

FERN comprises over 165 laboratories, including 35 radiological laboratories. ORA/WEAC in Winchester, MA, is the lead FDA field laboratory for the analysis of radionuclides in foods, drugs, and medical devices.

FERN radiological laboratory contact information, laboratory capability, and capacity are maintained on the FoodSHIELD website (www.foodshield.org).

Laboratory analyses, capability, and capacity will be dependent upon the type and scope of the emergency (i.e., the source of contamination, radionuclides, foods that may be contaminated, and levels of contamination). Sample throughput is variable. For example, at the onset of the emergency, samples may be triaged through screening methods, or the use of gamma radioactivity analysis may be extremely rapid at the FDA DIL. In comparison, alpha and beta activity measurements in foods may take several days to complete.

Samples may be collected from onsite authorities or FDA, State, or local investigators and shipped to WEAC or FERN-activated laboratories.

Services Provided to FDA/ORA Personnel

WEAC is responsible for the health and safety of workers in the field during a radiological/nuclear event. As such they provide the following services:

- Personal Dosimetry and Monitoring
 - Thermoluminescent dosimeters (TLDs) are provided to field analysts and import investigators. The FDA/ORA TLD personal dosimetry program is managed through the ORA Radiation Safety Officer at WEAC.
 - WEAC provides whole-body counting (i.e., the measurement of radioactivity within the whole body). This service is offered to FDA personnel who may have ingested or inhaled gamma-emitting radioactive material. Contact the FDA/ORA Radiation Safety Officer for services.
- ***Radiation Detection During Border Exams of Imported Products.*** FDA/ORA investigators performing inspections at ports of entry are equipped with personal radiation detectors. SOPs (e.g., Notification and Response Procedures) are provided to the investigators. FDA/ORA/WEAC and ORA/Division of Field Investigations (DFI) manage this program.

WEAC Emergency Preparedness Plan (Extract)

WEAC promotes laboratory readiness to analyze samples for radioactive contamination and advance preparation guides through WEAC SOPs. These SOPs are readily available on the FDA/ORA/WEAC intranet website. The SOPs provide the following:

- WEAC Contact Information
- Laboratory Capability and Capacity
- Investigational Guidance
 - Sample Collection Guidance and Instructions
 - Shipping Instructions
- Radiation Safety Program Information
 - Radiation Safety Information and Guidance
 - Personal Monitoring Information and Guidance

APPENDIX B:

ACTIVATION/NOTIFICATION OF THE ADVISORY TEAM FOR NUCLEAR/RADIOLOGICAL EMERGENCIES

Background

FDA is a member, and currently the chair, of the Federal Advisory Team—an interagency advisory group that can be activated during radiological incidents to assist other Federal, State, tribal, and local organizations by interpreting radiological data and making PARs to protect the public. Alert and notification activities for the Advisory Team are the responsibility of the agency chairing the team. According to the current NRF NRIA, any external organization can request the assistance of the Advisory Team by contacting the CDC EOC. Until such time as the NRIA is revised, calls to the CDC’s EOC will be transferred to the FDA EOC, who will conduct further notification of the other member agencies (i.e., USDA, EPA, and CDC) that Advisory Team assistance has been requested. Requests may also be made directly to the FDA EOC. FRMAC will also request the Advisory Team upon its activation through the FDA EOC. This document describes the internal notification and activation procedures that the FDA EOC will follow after receiving notification from the CDC EOC or directly from an outside entity.

Scope

This document applies to any radiological incident for which Federal assistance has been requested and Advisory Team participation (deployment or consultation) is needed.

Procedure

1. As described in the 2008 version of the NRIA, the requesting call may be received by the CDC DEOC. If the incoming request is received directly by FDA from a different entity, the process begins at Step 3 below.
2. The CDC DEOC staff records the caller’s basic information (e.g., name, organization, two contact numbers, nature of request/notification, deployment logistics [if known]) and either transfers the call to the FDA After-Hours Emergency Line (**1-866-300-4374** or **301-796-8240**) or provides the FDA After-Hours Emergency Call Center (Call Center) number to the caller. The first method is preferred.
3. During normal duty hours (8:30 a.m. to 5:00 p.m. Eastern Time, weekdays), the incoming call is received by FDA OEO staff and referred to FDA OCM Director or OEO Director for follow-up.
4. During non-duty hours (5:00 p.m. to 8:30 a.m. Eastern Time, weekdays; 5:00 p.m. Eastern Time Friday through 8:30 a.m. Eastern Time Monday; and Federal holidays), the incoming call is received by the FDA After-Hours Emergency Call Center staff (contractor). Call Center staff record the caller’s basic information (e.g., name, organization, two contact numbers, nature of request/notification, deployment logistics [if known]).
5. The Call Center “warm transfers” the call to OEO LDO, or Alternate LDO, in accordance with established Call Center procedures.
6. The Call Center sends automated email message to FDA Emergency Operations (emergency.operations@fda.hhs.gov) advising all OEO staff of the LDO notification.
7. The LDO contacts the Advisory Team Chair by telephone.
8. If the Advisory Team Chair is unavailable, the LDO contacts an alternate FDA Advisory Team member, in the order specified in the Advisory Team tab of the OCM/OEO Redbook.

9. Upon reaching the Advisory Team Chair or an alternate, the LDO confirms that they would like the other Advisory Team agencies notified, and also determines if the Advisory Team would like OEO to set up a conference call with the other Advisory Team agencies, along with the desired call time, allowing sufficient lead time for required notifications to be made.
10. The LDO notifies the OCM Director and OEO Director by telephone.
11. The OCM or OCM/OEO Director will initially make telephone contacts with the following individuals in FDA and apprise of the events and activities as they are known:
 - a. CFSAN Emergency Coordinator, with a request that they contact CFSAN's Radiological SMEs.
 - b. Regional Emergency Coordinator(s) and RFDD(s) for the Region(s) where incident occurred.
12. The CFSAN Emergency Coordinator will notify the EOC whether CFSAN has representation on the Advisory Team (in reachback status) and/or identify other SMEs that are available to support the Advisory Team.
13. The RFDD(s) will be asked to contact the RRHR(s) and make arrangements for their deployment to the site of the emergency where they will coordinate with other onsite Advisory Team members.
14. The LDO sends a summary email to FDA Emergency Operations (emergency.operations@fda.hhs.gov) indicating that the call was received and successfully referred to the Advisory Team Chair or alternate member.
15. The Advisory Team representative confirms that the LDO should notify the other Advisory Team member agency EOCs (e.g., CDC, EPA, USDA) to inform them of the request for Advisory Team assistance/activation. If requested, the LDO contacts agency EOCs by email and follow-up telephone call and provides basic incident information and instructions for a conference call at the specified time. EOC telephone numbers and conference call numbers are maintained in the Advisory Team tab of the OCM/OEO Redbook.
16. The LDO notifies HHS SOC of the incoming request via email (hhs.soc@hhs.gov).
17. OCM/OEO management notifies the FRPCC Chair of the incoming request via email.
18. The LDO notifies the following individuals by email:
 - a. RFDD for the affected Region.
 - b. Regional Emergency Response Coordinator (RERC) for the affected Region.
 - c. All RRHRs.
 - d. ORA headquarters Emergency Response Coordination Group (ERCG).
 - e. DD for the affected District.
 - f. District Emergency Response Coordinator (DERC) for the affected District.
 - g. Director, Investigations Branch (DIB) for the affected District.
 - h. CFSAN Emergency Coordinator.
 - i. Counselor to the Commissioner.
 - j. ORA Weekend Duty Manager (if applicable) via email.

If requested to do so by Advisory Team Chair or designated representative, the LDO includes all remaining FDA Advisory Team members and CFSAN radiological SMEs on this notification.



19. The LDO sends an information-only email to all Center/Office emergency coordinators, all RFDDs, all RERCs, all DERCs, all DDs, and all DIBs.
20. OCM/OEO management reviews the FDA EOP, Appendix C, “FDA Mission Assignment Sub-Taskings” and initiates appropriate notifications/actions to support any contemplated FEMA/HHS mission assignment sub-taskings for Advisory Team deployment.
21. The LDO and/or OCM/OEO management maintain communications with the Advisory Team Chair or designated representative to assist with any follow-up actions required.
22. FDA EOC operational level may change according to existing procedures (see FDA EOP).¹⁵
23. For events coordinated in the FDA EOC by an IMG, the agency’s Radiological Emergency Response Unit leader will identify personnel at FDA headquarters to participate in Advisory Team conference calls and meetings to provide situational awareness and to represent the needs of the EOC for information (e.g., radiological data, maps, etc.).

NOTE: After consultation with the OEO or OCM Director, LDO duties outlined above may be distributed among other OCM managers or emergency coordinators in the interest of time.

References

- NRF
- NRF NRIA
- Advisory Team CONOPS
- FDA EOP

¹⁵ For any radiological incident for which Federal assistance has been requested, including the Advisory Team, it is likely that the FDA EOC activation level would be increased and an IMG established.



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APPENDIX C: PROTECTIVE ACTIONS

Protective Action Guides

PAGs are projected (estimated) dose levels to individuals in the general population at which a recommendation for protective action may be warranted. FDA has developed one set of PAGs for the ingestion pathway. The current PAGs are 5 millisievert (mSv) for committed effective dose equivalent or 50 mSv committed dose equivalent to an individual tissue or organ, whichever is more limiting. The EPA maintains PAGs for all exposure pathways, publishing them in their *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents* (publication number 400R92001, available at EPA's website, www.epa.gov/radiation/docs/er/400-r-92-001.pdf). EPA's PAGs are currently in revision and a draft has been released for interim use that incorporates FDA's current food guidance document, *Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies*, August 13, 1998 (available at www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM094513.pdf).

Derived Intervention Levels

The DIL refers to the concentration of radioactive contamination present in food that, if ingested at this level over a specified time, may result in the individual receiving a projected dose equal to the PAG. FDA uses the internationally accepted units of becquerel per kilogram (Bq/kg) to express DILs, but it is common for radioactivity levels to also be expressed in units of picocuries per kilogram (pCi/kg) (1 Bq equals 27 pCi). The criteria used to calculate DILs include established dose coefficients for different age groups in the population, the fraction of food intake assumed to be contaminated, and the quantity of food consumed by that age group in the specified time period. The lowest calculated value across all age groups and target organs is designated as the DIL for that radionuclide. The assumptions used to calculate the DILs are extremely conservative. Thus, using the DILs to control food intake would realistically result in a person receiving only a fraction of the PAG dose.

FDA has calculated and published DILs for the radionuclides expected to deliver the major portion of radiation dose via the ingestion pathway during the first year following an emergency. The types of situations for which FDA has calculated DILs are: a release from a nuclear power plant, nuclear fuel reprocessing plant, or nuclear waste storage facility; the detonation of a nuclear weapon; transportation accidents; and release of material from radioisotope thermoelectric generators or heater units.

Table C-1 depicts the DILs for the nine principal radionuclides expected to be major contributors from these types of emergencies. The DIL for each radionuclide group is applied independently. The DILs apply to foods as prepared for consumption. For dried or concentrated products, such as powdered milk or concentrated juices, one should adjust by an appropriate reconstitution factor. For spices, consumed in very small quantities, a dilution factor of 10 is recommended. DILs for other types of emergencies and the other radionuclides such as terrorist activities can be determined using the same methodology.

Table C-1. Principal Radionuclides and Corresponding DILs

Radionuclide	DIL (Bq/kg)	DIL (pCi/kg)
Sr-90	160	4,300
I-131	170	4,600
Cs-134 + Cs-137	1,200	32,000
Pu-238 + Pu-239 + Am-241	2	54
Ru-103 + Ru-106	$\text{Ru-103} + \text{Ru-106} = 1$ $(C_3 / 6,800) + (C_6 / 450) < 1$	$\text{Ru-103} + \text{Ru-106} = 1$ $(C_3 / 180,000) + (C_6 / 12,000) < 1$

Sr = Strontium
I = Iodine

Cs = Cesium
Pu = Plutonium

Am = Americium
Ru = Ruthenium

C₃ and C₆ = the Concentrations



Protective Action Recommendations

PARs refer to specific actions that public health officials or members of the public can take to limit the radiation dose from eating contaminated products. These recommendations focus on steps to avoid or reduce radionuclide contamination in or on food and animal feed.

Public health officials or members of the public can take protective actions before and/or after contamination is confirmed. An example of a protective action taken before confirmation of contamination is a temporary, indefinite restriction on the movement of food out of a possibly contaminated region. With confirmation of contamination and specific identification of the contaminant, other protective actions may become appropriate. Assessing the extent and impact of contamination of food includes measuring activity levels in sampled foodstuffs and comparing against the relevant DILs. Depending on the specific circumstances, individuals can take a variety of protective actions, including holding of food for a specified time period to allow contamination to diminish through normal radioactive decay, removing surface contamination by washing and diverting or destroying contaminated food. Federal Agencies may receive a request to provide PARs to State and local public health authorities. If there is a request for PARs for FDA-regulated products, FDA's RRHR, the agency's onsite liaison to the Advisory Team, works with the Advisory Team and in consultation with other FDA scientific and policy experts to develop them. PARs are given to State and local authorities via appropriate on-scene NIMS procedures. State and local officials determine specific protective actions for implementation.

APPENDIX D:

MEMORANDUM OF UNDERSTANDING

A memorandum of understanding (MOU) is a critical component of any formal arrangement for cooperation between two or more entities. An MOU usually describes, in broad general terms, an area of mutual interest or concern that two or more agencies or organizations may cooperatively address. MOUs generally do not include specific information regarding detailed scope of work or the exchange of funds or human resources.

A complete listing of MOUs or other written cooperative arrangements with States, other Federal Agencies and foreign government counterparts, and the World Health Organization (WHO) can be found at www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/default.htm.

MOU with the Nuclear Regulatory Commission

On December 12, 2002, an earlier MOU between FDA and the NRC was renewed for an indefinite time. It clarifies the respective roles of each agency in regulating the safe use of radiopharmaceuticals and sealed sources or devices containing radioactive material. As a result, the NRC and FDA have established LNOs and identified key management and technical personnel for coordinating responses to emergencies or specific events of mutual interest. They have conducted joint inspections of medical events involving device failures and human- or computer-generated errors. Additionally, senior management meetings between the two agencies are conducted annually.



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APPENDIX E:

FDA RESPONSIBILITIES DURING RADIOLOGICAL INCIDENTS

This appendix provides an overview of the FDA components that would respond to a radiological emergency and the responsibilities each Office would have during the response and recovery phases (see **Table E-1**).

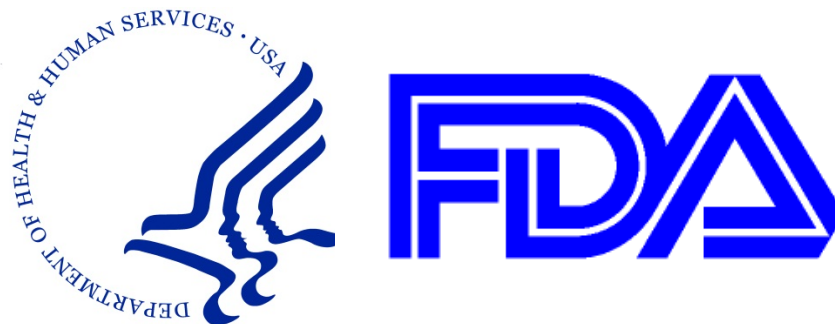
Table E-1. FDA Responsibilities for Radiological Incidents

OCM/ OEO ¹	Office of Foods and Veterinary Medicine (OFVM)/CFSAN	OFVM/ CVM	OEA	ORA	OO
<ul style="list-style-type: none"> Manage FDA's EOC Monitors emergency situations Coordinates overall agency response operations 	Coordinate with DHS Critical Infrastructure Food and Agriculture Sector	Serve as POC for veterinary industry	Respond to external inquiries: <ul style="list-style-type: none"> Media Consumer Industry Health Professionals 	Represent FDA on the Advisory Team	Represent FDA on the Advisory Team
Serve as POC for interagency communication and coordination	Coordinate and communicate with the food and agriculture industry	Serve as POC for feed supply incidents	Coordinate with HHS ASPA, ASPR, and the CDC on public messaging	Provide RRHRs	
Communicate with the HHS SOC	Serve as POC for food and agriculture industry	Ensure safety of feed for animals (food production)	Represent FDA on NICCL, SICCL, and PICCL conference calls and other agency public affairs offices as needed	Conduct 50-State calls (OP)	
Coordinate ESF/ Recovery Support Function (RSF) MAs	Ensure the safety of food for humans		Develop agency public messaging		
Participate in the 50-State calls			Serve as POC for interagency communication and coordination of messaging		
Monitor the NICCL, SICCL, and PICCL conference calls					
Coordinate with White House/National Security Staff					
Coordinate with Advisory Team; provides scientific advice for a radiological incident					
Communicate and coordinate with WEAC and FERN					

¹ These functions may be performed by an IMG, when activated.



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**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. Food and Drug Administration**

Pandemic Influenza Annex to the FDA Emergency Operations Plan

Version 2.0

March 2014

OFFICE OF CRISIS MANAGEMENT

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Pandemic Influenza Annex



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PANDEMIC INFLUENZA ANNEX TABLE OF CONTENTS

A. Introduction.....	PI Annex-1
A.1 Mission	PI Annex-1
A.2 Purpose	PI Annex-1
A.3 Scope and Applicability	PI Annex-2
A.4 Planning Assumptions	PI Annex-3
A.5 Activation	PI Annex-4
A.6 Supersedece	PI Annex-4
B. Concept of Operations	PI Annex-5
B.1 Emergency Authorities	PI Annex-5
B.2 Emergency Operations Phases	PI Annex-5
B.2.1 Prevention and Protection	PI Annex-5
B.2.1.1 Surveillance and Detection	PI Annex-5
B.2.1.2 Consumer Product Protection	PI Annex-5
B.2.1.3 Medical Countermeasures	PI Annex-6
B.2.1.4 Increased Surveillance of FDA-Regulated Pandemic Influenza Medical Products	PI Annex-6
B.2.2 Response	PI Annex-6
B.2.2.1 Gain and Maintain Situational Awareness	PI Annex-6
B.2.2.1.1 Alert and Notification	PI Annex-6
B.2.2.1.2 Administrative Alert and Notification	PI Annex-6
B.2.2.2 Coordination of Response Actions	PI Annex-6
B.2.2.2.1 FDA Headquarters Response	PI Annex-6
B.2.2.2.2 Medical Countermeasures Expanded Access and EUA	PI Annex-7
B.2.2.3 Demobilization	PI Annex-7
B.2.3 Recovery	PI Annex-7
C. Organization and Assignment of Responsibilities	PI Annex-8
C.1 Office of the Commissioner	PI Annex-9
C.1.1 Office of the Chief Counsel	PI Annex-10
C.1.2 Office of Legislation	PI Annex-10
C.1.3 Office of Policy and Planning	PI Annex-10
C.1.4 Office of the Counselor to the Commissioner	PI Annex-10
C.1.4.1 Office of Crisis Management	PI Annex-11
C.1.5 Office of External Affairs	PI Annex-12
C.1.5.1 Web and Digital Media Staff	PI Annex-13
C.1.5.2 Office of Communications	PI Annex-13
C.1.5.3 Office of Media Affairs/Media Relations	PI Annex-13
C.1.5.4 Office of Health and Constituent Affairs	PI Annex-14
C.2 Office of the Chief Scientist	PI Annex-15
C.2.1 Office of Counterterrorism and Emerging Threats	PI Annex-15



C.3	Office of Operations	PI Annex-16
C.3.1	Office of Finance, Budget, and Acquisition	PI Annex-18
C.3.1.1	Office of Budget	PI Annex-18
C.3.1.2	Office of Acquisitions and Grants Services.....	PI Annex-19
C.3.1.3	Office of Financial Operations	PI Annex-20
C.3.1.3.1	Office of Financial Management.....	PI Annex-20
C.3.2	Office of Information Management.....	PI Annex-20
C.4	Office of Foods.....	PI Annex-24
C.4.1	Coordinated Outbreak Response and Evaluation	PI Annex-24
C.4.2	Center for Food Safety and Applied Nutrition	PI Annex-24
C.4.3	Center for Veterinary Medicine	PI Annex-26
C.5	Office of Medical Products and Tobacco	PI Annex-27
C.5.1	Office of Special Medical Programs.....	PI Annex-27
C.5.1.1	Office of Combination Products	PI Annex-27
C.5.2	Center for Drug Evaluation and Research	PI Annex-27
C.4.3	Center for Biologics Evaluation and Research	PI Annex-29
C.5.4	Center for Devices and Radiological Health	PI Annex-31
C.6	Office of Global Regulatory Operations and Policy.....	PI Annex-33
C.6.1	Office of International Programs	PI Annex-33
C.6.2	Office of Regulatory Affairs	PI Annex-34
C.6.2.1	Office of Regulatory Affairs Laboratories.....	PI Annex-35
D.	Direction, Control, and Coordination	PI Annex-36
D.1	Command Staff	PI Annex-37
D.1.1	Pandemic Influenza-Specific Liaisons	PI Annex-37
D.1.2	Legal Advisor	PI Annex-37
D.1.2.1	Legal Group	PI Annex-37
D.2	General Staff	PI Annex-37
D.2.1	Operations Section.....	PI Annex-37
D.2.1.1	Drug Group	PI Annex-38
D.2.1.1.1	Antiviral Team	PI Annex-38
D.2.1.1.2	Expired Drugs Team	PI Annex-38
D.2.1.1.3	Drug Shortage Team	PI Annex-38
D.2.1.1.4	Adverse Drug Events Team.....	PI Annex-38
D.2.1.2	Biologics Group.....	PI Annex-38
D.2.1.2.1	Vaccine Team	PI Annex-38
D.2.1.2.2	Blood Team.....	PI Annex-39
D.2.1.3	Medical Device Group.....	PI Annex-39
D.2.1.3.1	In-Vitro Diagnostics Team.....	PI Annex-39
D.2.1.3.2	Personal Protective Equipment and Other Devices Team	PI Annex-39
D.2.1.3.3	Shortage Team	PI Annex-40
D.2.2	Logistics Section	PI Annex-40
D.2.2.1	Employee Health Advisor.....	PI Annex-40



E. Communications and Information Management.....	PI Annex-41
F. Authorities and References	PI Annex-42
F.1 National Strategies.....	PI Annex-42
F.2 Federal Plans and Guidance.....	PI Annex-42
F.3 FDA Supporting Documentation	PI Annex-43
Appendix A: Protection of Workers: Guidance on Preparing the Workplace and Workers for an Influenza Pandemic	PI Annex-45

LIST OF FIGURES

Figure A-1. Continuum of Pandemic Phases.....	PI Annex-2
Figure D-1. Possible Pandemic Influenza IMG Structure	PI Annex-36



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A. INTRODUCTION

Pandemic influenza has the potential to cause adverse health effects for large segments of the population and animals, either directly due to exposure to the virus or indirectly as a result of the social and economic disruptions caused by the pandemic. To mitigate the consequences of pandemic influenza, the U.S. Food and Drug Administration (FDA) must be prepared to respond, with potentially limited staff, to a greater-than-normal demand and a public health need for safe and effective medical products to prevent and treat pandemic influenza, as well as other FDA-regulated products.

The *Pandemic Influenza Annex to the FDA Emergency Operations Plan (EOP)* establishes a single, comprehensive framework for the agency's management of pandemic influenza emergencies. It provides the measures, operating structures, roles and responsibilities, and mechanisms for direction and coordination of FDA resources before, during, and while recovering from an outbreak. The *Pandemic Influenza Annex* is compatible with the scalable, flexible, and adaptable Federal Government emergency coordinating structures of the *National Response Framework (NRF)* and is consistent with the concepts, principles, and terminology of the National Incident Management System (NIMS)¹ and the FDA EOP. The *Pandemic Influenza Annex* is to be used to assist FDA in conducting response operations for any pandemic influenza emergency.

A.1 MISSION

During an influenza pandemic emergency, FDA's mission may expand to include performance of specific incident-related functions, such as:

- Facilitating the availability of approved and unapproved medical countermeasures, including evaluating and authorizing, as appropriate, emergency use authorizations (EUAs) for vaccine and antiviral medical countermeasures, personal protective equipment (PPE), and in-vitro diagnostics (IVDs).
- Working with manufacturers to expedite the development, licensure (if possible), and lot release of a vaccine specific to the pandemic strain.
- Monitoring the availability of critically needed FDA-regulated medical products, such as respiratory protection devices.

A.2 PURPOSE

The purpose of the *Pandemic Influenza Annex* is to add more detailed guidance to the FDA EOP to provide a coordinated response to the adverse impact an influenza pandemic would have on FDA and the industry and products it regulates. To accomplish this, the *Pandemic Influenza Annex* describes specific actions that FDA's organizational components and personnel will take when responding to a pandemic influenza incident and enhances the agency's emergency preparedness and response capabilities.

The *Pandemic Influenza Annex*:

- Is compatible with and expands on the FDA EOP.
- Defines the FDA influenza pandemic emergency operating structure and identifies the essential tasks of all FDA organizational components involved in prevention, protection, response, and recovery efforts.
- Provides mechanisms for vertical and horizontal command, control, coordination, and communication.
- Ensures consistency with nationally recognized incident management policy and guidance.

¹ For more information on the NRF and NIMS, refer to the "Authorities and References" section of the FDA EOP.

A.3 SCOPE AND APPLICABILITY

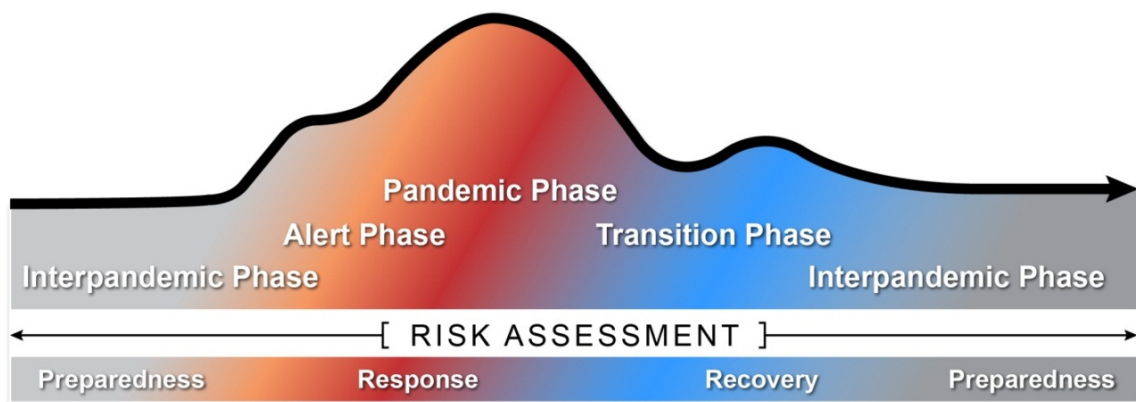
This annex applies to any pandemic influenza incident for which FDA provides assistance under Emergency Support Function (ESF) #8 of the NRF, the *National Strategy for Pandemic Influenza*, the *National Strategy for Pandemic Influenza – Implementation Plan*, or under its own authority under the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), as amended.

This annex applies to FDA’s response activities that will assist in:

1. Stopping, slowing, or otherwise limiting the spread of a pandemic to the United States.
2. Limiting the domestic spread of a pandemic and mitigating disease, suffering, and death.
3. Sustaining infrastructure and mitigating the impact on the economy and the functioning of society.

For the purpose of this annex, an influenza pandemic incident occurs when a novel strain of influenza virus emerges with the ability to infect and efficiently spread among humans. Because humans lack immunity to the new virus, a worldwide epidemic or pandemic can occur.

This *Pandemic Influenza Annex* guides FDA personnel, explaining FDA’s response activities and procedures for a cluster of novel influenza cases in verified human-to-human transmission during the World Health Organization (WHO) phases of influenza pandemic, including the alert phase and pandemic phase (see **Figure A-1**). WHO has developed a *risk-based approach to pandemic influenza based on a continuum*, which shows the phases in the context of preparedness, response, and recovery as part of an *all-hazards approach to emergency risk management*. In the event of an influenza pandemic emergency, FDA headquarters and Regional/District staffs will follow these response procedures.



Definitions of Phases of Pandemic Flu Within the Continuum	
Interpandemic Phase	This is the period between influenza pandemics.
Alert Phase	This is the phase when influenza caused by a new subtype has been identified in humans. Increased vigilance and careful risk assessment, at local, national, and global levels, are characteristic of this phase. If the risk assessments indicate that the new virus is not developing into a pandemic strain, a de-escalation of activities toward those in the interpandemic phase may occur.
Pandemic Phase	This is the period of global spread of human influenza caused by a new subtype. Movement between the interpandemic, alert, and pandemic phases may occur quickly or gradually as indicated by the global risk assessment, principally based on virological, epidemiological, and clinical data.
Transition Phase	As the assessed global risk reduces, de escalation of global actions may occur, and reduction in response activities or movement toward recovery actions by countries may be appropriate, according to their own risk assessments.

Source: *Pandemic Influenza Risk Management – WHO Interim Guidance*, World Health Organization, 2013
www.who.int/influenza/preparedness/pandemic/influenza_risk_management/en/index.html

Figure A-1. Continuum of Pandemic Phases

A.4 PLANNING ASSUMPTIONS

The *Pandemic Influenza Annex* is based on the following planning assumptions:

- During the interpandemic phases, FDA will perform its routine functions.
- During the alert phase, in addition to routine functions, many FDA Offices and Centers may begin performing pandemic influenza response activities described in this annex.
- During the pandemic phase (i.e., U.S. pandemic period), routine functions may continue based on staffing availability; however, pandemic influenza response activities will take priority.
- Susceptibility to the pandemic influenza virus will be universal.
- An influenza pandemic will cause simultaneous outbreaks across the United States, limiting the ability to transfer assistance from one area to another.
- Widespread illness in communities may increase the likelihood of significant shortages of personnel (in health and non-health sectors) who provide other essential community services.
- A pandemic will pose significant challenges to FDA employees responsible for sustaining FDA's essential functions due to widespread absenteeism.
- An influenza pandemic may require FDA staff members to sustain some essential functions from home.
- Some information systems supporting FDA operations may not be available.
- Due to the uniqueness of their positions, not all essential employees will have a backup.
- The adverse impact of pandemic influenza on the availability of safe and effective FDA-regulated products requires an immediate response by FDA. Protection of the affected or potentially affected population is the highest priority during response operations.
- Epidemics would last 6 to 8 weeks in affected communities. Multiple waves of illness (periods during which community outbreaks occur across the country) are likely to occur with each wave lasting 2 to 3 months. As many as 40 percent of FDA employees and FDA-regulated industry employees in a geographic area could be absent from work at any point during a pandemic. This could also adversely impact the donor pool necessary for availability of blood and tissue products.
- Greater product demand and increased worker absenteeism in the FDA-regulated industry could lead to shortages of commercial food products and medical products that are used to prevent and treat pandemic influenza.
- Quarantining of critical FDA-regulated facilities and large geographic areas may result. This may affect other countries, requiring extensive coordination with State, local, and foreign governments in conjunction with other Federal Agencies.
- FDA U.S. Public Health Service (USPHS) Commissioned Corps personnel may be deployed, as necessary, to support U.S. Department of Health and Human Services (HHS) pandemic influenza response efforts.
- Regional Food and Drug Directors, District Directors, and Center/Office Directors may activate their individual organizational component's emergency operations or pandemic influenza plan without activation of the *Pandemic Influenza Annex*.



A.5 ACTIVATION

The Public Health and Medical Services (ESF #8) response to an outbreak of pandemic influenza will be directed by the HHS Office of the Secretary in coordination with the U.S. Department of Homeland Security (DHS), which is responsible for managing the U.S. Government (USG) response. FDA is a subordinate Operating Division (OPDIV) of HHS, and it will align its response activities with those of HHS. FDA will use the full spectrum of its resources to accomplish assigned roles, responsibilities, functions, goals, and missions.

This annex will be consulted and implemented together with the FDA EOP when there is an influenza pandemic threat abroad or in North America or a declaration of a pandemic by WHO.

A.6 SUPERSEDEANCE

This *Pandemic Influenza Annex to the FDA EOP* (2014) supersedes the *FDA EOP Pandemic Influenza Annex* (2010).

B. CONCEPT OF OPERATIONS

The scope of FDA emergency operations response to an influenza pandemic involves a wide array of products regulated simultaneously by the agency. The following concept of operations (CONOPS) section of this annex describes the principal authorities governing agency emergency functions that FDA conducts to perform its incident-related influenza pandemic operations.

B.1 EMERGENCY AUTHORITIES

FDA emergency authorities are listed in the FDA EOP.

B.2 EMERGENCY OPERATIONS PHASES

The following phases comprise the entire spectrum of FDA emergency operations: ***Prevention, Protection, Mitigation, Response, and Recovery***. When a global pandemic may occur or does occur, FDA employees are expected to follow the activities described in the FDA EOP, *Section B.2, “Emergency Operations Phases.”* Although emergency operations may involve each of these phases over the course of a pandemic influenza incident, the nature and severity of an event and FDA’s organizational component(s) responding will determine the specific order, actions, and responsible parties required for each.² The following sections describe additional resources available during FDA’s emergency operations for Prevention and Protection specific to a potential pandemic or pandemic event.

B.2.1 *Prevention and Protection*

B.2.1.1 Surveillance and Detection

During a pandemic influenza event, FDA may use the following surveillance and detection systems:

- Adverse Event Reporting System (AERS)
- Biological Product Deviation Reporting (BPDR) System
- Center for Devices and Radiological Health (CDRH) Product Availability (Shortages) Database
- Emergency Operations Network – Incident Management System (EON-IMS)
- Manufacturer and User Facility Device Experience (MAUDE) System
- MedWatch
- National Biosurveillance Integration System (NBIS)
- New Drug Application (NDA) Field Alert Program
- Veterinary Adverse Drug Experience (ADE) Reporting System

For a complete listing of surveillance and detection systems, refer to the FDA EOP, Table B-1.

B.2.1.2 Consumer Product Protection

In addition to the activities designated to deter intentional and unintentional acts against FDA-regulated products and to protect consumers from potential public health hazards, as described in the FDA EOP, FDA takes the following actions during an influenza pandemic:

- Expedited review of applications for vaccines, antivirals, masks, and IVDs.
- Aggressive surveillance to identify and take action to stop fraudulent promotion of products to prevent, diagnose, or treat influenza.

² Refer to FDA EOP, Section C, *Organization and Assignment of Responsibilities*, for an overview of FDA organizational component roles and responsibilities during an emergency.

B.2.1.3 Medical Countermeasures

FDA Centers and Offices shall perform the general functions related to medical countermeasures mentioned in the FDA EOP, *Section B.2.1.3*, “Medical Countermeasures.”

B.2.1.4 Increased Surveillance of FDA-Regulated Pandemic Influenza Medical Products

During an influenza pandemic, FDA may increase its surveillance of FDA-regulated medical products used to prevent, diagnose, or mitigate adverse health effects of the pandemic influenza virus. Examples of such products include antivirals, vaccines, respiratory protection devices, other types of PPE, and IVD kits. Increased surveillance may include, but is not limited to, pharmacovigilance, such as tracking of vaccine adverse events or emergence of antiviral resistance; product quality, such as tracking of counterfeit products and fraudulent claims; and product availability, such as shortages of antivirals, masks, and essential medical material. The increased surveillance could be a result of conditions, such as the use of a product by a larger or different population; the use of products for other than their labeled indication; or concerns about the potential development of resistance to a product, such as antivirals or antibiotics. A specific concern is resistance developing to any antiviral drug in use for the pandemic influenza strain.

B.2.2 Response

B.2.2.1 Gain and Maintain Situational Awareness

B.2.2.1.1 Alert and Notification

FDA employees are expected to follow the activities described in the FDA EOP, *Section B.2.2.1.1*, “Alert and Notification.” In addition, FDA’s Office of Operations is to be notified of a pandemic event.

B.2.2.1.2 Administrative Alert and Notification

The FDA Office of Management (OM), within the Office of the Commissioner (OC), serves as the agency’s focal point for distributing information to agency staff concerning their safety and health to maintain staff agency mission support. Examples of such information include:

- Flexible workplace agreement activities.
- PPE and other medical countermeasures, such as vaccines and antivirals.
- Building closures.

B.2.2.2 Coordination of Response Actions

FDA response coordination during a pandemic will follow the FDA EOP, which will be augmented by the following coordination and response activities.

B.2.2.2.1 FDA Headquarters Response

The FDA OC Offices, Centers, and Office of Regulatory Affairs (ORA) will follow the FDA EOP, *Section B.2.2.3*, “Coordination of Response Actions,” which contains contacts for information dissemination, resource coordination, and priority setting. In addition, the following steps will be taken for a pandemic:

- Examine all foreign travel and restrict if necessary.
- Review plans and update all essential personnel listings.
- Ensure employees are familiar with emergency procedures.



B.2.2.2.2 Medical Countermeasures Expanded Access and EUA

FDA response regarding medical countermeasures availability and use will follow the FDA EOP, *Section B.2.2.3.5*, “Medical Countermeasures: EUA and Expanded Access” and will be augmented by OC EUA standard operating procedure (SOP).

B.2.2.3 Demobilization

The FDA OC Offices, Centers, and ORA will follow the FDA EOP, *Section B.2.2.4*, “Demobilization,” and return to an agency-wide Task Force structure led by the Office of Counterterrorism and Emerging Threats (OCET).

B.2.3 Recovery

The FDA OC Offices, Centers, and ORA will follow the FDA EOP, *Section B.2.3*, “Recovery,” and return to an agency-wide Task Force structure led by OCET.

C. ORGANIZATION AND ASSIGNMENT OF RESPONSIBILITIES

This section identifies the essential roles and functions of FDA Centers and Offices responding to a WHO alert or pandemic phase of an influenza pandemic. An essential employee is one who supports the accomplishment of a Center or Office's pandemic influenza essential functions. Centers and Offices have provided descriptions of their pandemic influenza essential functions for inclusion in this *Pandemic Influenza Annex*. For an employee to be considered essential to the accomplishment of pandemic influenza essential functions, the employee need not to be assigned work solely related to pandemic influenza response.

FDA Centers and Offices work closely with OC and with industry and Government partners to ensure the safety and efficacy of products for human use to prevent, diagnose, and treat the public health effects of pandemic influenza in the United States or worldwide, using novel and expeditious approaches to product regulation for optimized availability and use in all populations. During a pandemic response, issues may arise that involve more than one Center or Office. The Centers and Offices listed in this annex have additional tasks in supporting command and control operation during a pandemic that were not identified in the FDA EOP.

FDA Product Centers

FDA product Centers are responsible for the regulation of a defined set of products. Their professional staff includes both clinical and scientific experts. This expertise (analytical, laboratory, sampling procedures, subject matter expertise, and industry knowledge) is available for critical consultation should a pandemic influenza emergency occur. The National Center for Toxicological Research (NCTR) primarily conducts regulatory and applied research based on agency needs.

During an influenza pandemic, Centers are responsible for scientific evaluations and policy decisions (in cooperation with the FDA Emergency Operations Center [EOC], OCET, and ORA) in their respective program areas. FDA product Centers participate in an emergency response when the response includes, or may include, regulatory activities or products under their jurisdiction.

Common Center Pandemic Influenza Response Activities

Alert Phase and Pandemic Phase

- Increase monitoring of the safety and effectiveness of pandemic influenza medical counter-measures.
- Manage Center responsibilities.
- Provide administrative support services (e.g., information technology [IT]/Internet/local area network [LAN]/database, telephones, safety/security, budget execution, personnel, procurement, payroll, facility management, mail).
- Post and maintain critical information on Center home page.
- Examine all domestic/foreign travel and restrict if necessary.

C.1 OFFICE OF THE COMMISSIONER

Several organizational components within OC will play a significant role in supporting the agency's emergency response to a pandemic, such as the Office of Crisis Management (OCM), OCET, and the Office of External Affairs (OEA). In addition, other OC offices, such as the Office of the Chief Counsel (OCC), Office of International Programs (OIP), and Office of Operations (OO) [Office of Financial Management (OFM) and Office of Information Management (OIM)], can provide valuable assistance during FDA's response to a pandemic influenza emergency. A number of agency officials will be considered essential employees specific to influenza pandemic emergency response activities. They include the following:

OC Essential Employees	
<ul style="list-style-type: none"> ▪ Chief Counsel ▪ Chief of Staff ▪ Deputy Commissioner for Policy and Planning <ul style="list-style-type: none"> – Assistant Commissioner for Planning – Assistant Commissioner for Policy ▪ Counselor to the Commissioner ▪ Director, OCM ▪ Associate Commissioner for Special Medical Programs ▪ Associate Commissioner for External Affairs <ul style="list-style-type: none"> – Assistant Commissioner for External Affairs – Assistant Commissioner for Media Affairs ▪ Deputy Commissioner for Foods <ul style="list-style-type: none"> – Associate Commissioner for Food Protection – Chief Medical Officer and Director of Outbreaks – Senior Advisor to Director of Outbreaks ▪ Chief Scientist and Deputy Commissioner for Science and Public Health <ul style="list-style-type: none"> – Assistant Commissioner for Counterterrorism and Emerging Threats 	<ul style="list-style-type: none"> ▪ Deputy Commissioner for International Programs <ul style="list-style-type: none"> – Associate Commissioner for International Programs ▪ Chief Operating Officer <ul style="list-style-type: none"> – Director, Office of Budget – Director, OFM – Director, Office of Financial Services – Chief Information Officer – Director, Office of Human Resources – Director, Office of Security Operations ▪ Associate Commissioner for Regulatory Affairs ▪ Director, Center for Biologics Evaluation and Research ▪ Director, Center for Drug Evaluation and Research ▪ Director, Center for Devices and Radiological Health ▪ Director, Center for Food Safety and Applied Nutrition ▪ Director, Center for Veterinary Medicine ▪ Director, NCTR

In addition, it is expected that each Center and Office will maintain a detailed list of essential employees, to include necessary support staff for the essential employees. The detailed lists of essential employees will be responsible for the agency's continuity of business during an influenza pandemic and should be provided to OO.

C.1.1 Office of the Chief Counsel

OCC Essential Employees	
Associate General Counsel Deputy Chief Counsel Deputy Chief Counsel for Program Review Deputy Chief Counsel for Litigation Associate Deputy Chief Counsel for Drugs and Biologics Associate Deputy Chief Counsel for Devices, Food, and Veterinary Medicine Associate Deputy Chief Counsel for Litigation Executive Officer Senior Attorney	
One from each of these teams:	
Counseling Animal Products Biologics Devices Drugs Foods	Litigation Criminal Civil

OCC provides legal services involving the agency's regulatory activities. FDA lawyers support the agency's public health and consumer protection missions in two primary ways: handling litigation and providing counseling advice. OCC performs the same functions mentioned in the FDA EOP to support FDA's response to an influenza pandemic.

C.1.2 Office of Legislation

OL Essential Employees
Assistant Commissioner for Legislation Senior Advisor Supervisory Congressional Affairs Specialist Congressional Affairs Specialist (2)

The Office of Legislation (OL) provides Congress with information related to FDA's pandemic influenza response activities. OL performs the same functions described in the FDA EOP to support FDA's response to an influenza pandemic.

C.1.3 Office of Policy and Planning

The Office of Policy and Planning (OPP) is responsible for advising the Commissioner and other key agency officials on matters relating to FDA policies, rulemaking, and budgetary matters.

C.1.4 Office of the Counselor to the Commissioner

Office of the Counselor to the Commissioner Essential Employees
Counselor to the Commissioner

The Counselor to the Commissioner provides top-level leadership for FDA's emergency and crisis management policies and programs for pandemic influenza to ensure that a structure exists for rapid response to an influenza pandemic and to ensure the availability of FDA-regulated products needed to protect the public and prevent the spread of illness.

C.1.4.1 Office of Crisis Management

OCM Essential Employees
<p>Director, Office of Crisis Management</p> <p>Deputy Director, Office of Crisis Management</p> <p>Director, Office of Emergency Operations (OCM/OEO)</p> <p>Deputy Director, Office of Emergency Operations (OCM/OEO)</p> <p>Special Assistant to OCM Director</p> <p>Office of Emergency Operations Staff Supervisor (2)</p> <p>Emergency Coordinator (4)</p>

OCM consists of the OCM Director (and staff) and the Office of Emergency Operations (OEO). OCM and OEO are responsible for developing crisis and emergency management policies and procedures and managing agency emergencies when they occur. OCM manages the FDA EOC.

Emergency Operations Center

The FDA EOC will be the coordination point for FDA's response to a pandemic influenza incident.

OCM Response Activities
Alert Phase

- Maintain situational awareness of U.S. and worldwide pandemic influenza cases.
- Serve as agency focal point for coordination of all emergency response activities.
- Manage the agency's EOC and activate as needed.
- Manage the EON-IMS to provide agency officials access to large volumes of data related to pandemic events.
- Create geographic information system (GIS) maps to enhance response activities.
- Manage FDA's national Consumer Complaint Reporting system.
- Provide incident command training to OCM staff and other agency staff involved in emergency response activities.
- Participate in external emergency exercises, including pandemic influenza, and coordinate internal FDA exercises, including pandemic influenza.
- Participate in and support HHS Office of the Assistant Secretary for Preparedness and Response pandemic influenza planning activities.
- Identify agency pandemic influenza needs and goals in an agency priority setting process.
- Lead and/or assist in the development and implementation of FDA strategy for pandemic influenza.
- Lead the emergency preparedness and response component of the FDA Pandemic Influenza Preparedness Task Force.
- Lead the development of agency-wide pandemic influenza plans.
- Advise senior FDA officials on preparedness requirements for pandemic influenza.
- Provide updates to the Commissioner, other senior agency officials, and agency emergency coordinators regarding DHS, HHS, and Centers for Disease Control and Prevention (CDC) preparedness activities for potential U.S. pandemic influenza cases.



- Develop plans for FDA's EOC and prepare for possible activation of an Incident Management Group (IMG).

OCM Response Activities**Pandemic Phase**

- Perform all pandemic alert activities as appropriate.
- Give priority attention to pandemic influenza-related work and life-threatening/sustaining work associated with each of the activities listed above for pandemic alert phases.
- Communicate with other Federal, State, and local governments as they request technical and material support from FDA, and coordinate the agency's response to the requests.
- Provide FDA liaison to HHS Secretary's Operations Center (SOC) or other Federal EOCs as needed.
- Provide daily Situation Reports (SitReps) to the HHS SOC.
- Represent FDA on the HHS ESF #8 Pandemic Influenza Planning Group.
- Establish the FDA Incident Management System (IMS) and activate FDA's EOC if needed.
- Provide leadership for Planning and Operations Sections of IMS.
- Expedite triaging of incoming consumer complaints for adverse events associated with FDA-regulated products intended for preventing, treating, mitigating, or containing pandemic influenza.
- Provide guidance on proper handling, marking, processing, and storing of classified pandemic influenza materials.
- Work with OO/Office of Security Operations (OSO) to verify security clearances for FDA liaisons working at other Government EOCs, liaisons from other agencies working in FDA's EOC, and FDA staff working at Joint Operations Centers (JOCs) in the field.

C.1.5 Office of External Affairs**OEA Essential Employees**

Associate Commissioner for External Affairs
Deputy Director, Operations for External Affairs
Senior Management Officer

OEA works with outside groups in providing information related to FDA's pandemic influenza response activities and ensures up-to-date public health advice and guidance is provided to consumers and targeted audiences.

Web and Digital Media Staff

OMA/Web and Digital Media Staff Essential Employees
<p>Director, Web and Digital Media Staff Senior Advisor/Public Affairs Specialist Visual Information Specialist Program Analysts Technical Information Specialist</p>

The OC Web and Digital Media Staff oversees the content, design, and management of FDA's external website (www.fda.gov). OC Web and Digital Media Staff performs the same functions described in the FDA EOP to support FDA's response to an influenza pandemic.

C.1.5.1 Office of Communications

Office of Communications Essential Employees
<p>Assistant Commissioner for Communications Deputy Director Visual Information Specialist Writer/Editors Program Analyst</p>

- Collaborate with the FDA Office of Media Affairs (OMA), HHS, Assistant Commissioner for Communications, and the Deputy Assistant Commissioner for Communications to protect consumer well-being and decrease the risk of illness, disease, or death by ensuring that the official influenza pandemic messages of the USG reach FDA stakeholders.
- Develop and distribute *Consumer Update* articles that will help stakeholders and their audiences prepare for and manage pandemic influenza issues.
- Ensure Office of Communications staff is prepared for operations, as needed, including operations from staff members' homes and other offsite locations as necessary.

C.1.5.2 Office of Media Affairs/Media Relations

OMA Essential Employees
<p>Assistant Commissioner for Media Affairs Supervisory Public Affairs Specialist Program Support Specialist Press Officer</p>

OMA serves as FDA's primary liaison with the news media and develops much of the material FDA uses to communicate its public health and consumer protection messages to the public. OMA performs the following essential functions to support FDA's response to an influenza pandemic:

- Collaborate with the HHS Office of the Assistant Secretary for Public Affairs (ASPA) on, and ensure appropriate integration with, the official influenza pandemic messages of the USG (www.flu.gov).
- Maintain and update emergency/after-hours SOPs and contact lists for essential media relations personnel throughout FDA.
- Ensure SOPs involving clearance of communications materials include clear indicators of when materials are ready for release and who has the authority to approve those indicators; collaborate



with FDA Center communications staffs to develop boilerplate talking points that will allow quick messages to be released.

- Develop emergency backup plan that clearly indicates the primary contact, secondary contact, and contacts-on-deck in case of sickness, infrastructure failure, or other instances of unavailability.
- Ensure OIM has assessed the technical infrastructure and is prepared for 24 hours a day, 7 days a week (24/7) operations, operations from staff members' homes, and other offsite locations.

C.1.5.3 Office of Health and Constituent Affairs

Office of Health and Constituent Affairs Essential Employees
Director, Office of Special Health Issues
Deputy Director
Medical Advisor
Technology Information Specialist
Program Analyst

- Advise the Commissioner and other key FDA officials on matters related to patients, patient advocacy, health professionals, consumers, State and Federal activities, and industry issues.
- Assist in the planning, administration, development, and evaluation of FDA policies related to patient advocacy and health professional organizations, consumers, States, and industry on serious and life-threatening issues.
- Serve as a liaison between FDA and stakeholder organizations to educate various constituents on FDA-related issues and activities.
- Collaborate with FDA, HHS, and health professional and patient advocacy organizations to ensure the official influenza pandemic messages of the USG reach health professional and patient advocacy organizations.
- Deliver and distribute health professional articles that will help stakeholders and their audiences prepare for and manage pandemic influenza issues.
- Organize teleconferences to inform stakeholders of topics of interest for pandemic influenza (e.g., EUAs, shortages, compounding).
- Ensure staff is prepared for operations, as needed, including operations from staff members' homes and other offsite locations, as necessary.



C.2 OFFICE OF THE CHIEF SCIENTIST

OCS Essential Employees

Chief Scientist and Deputy Commissioner for Science and Public Health

The Office of the Chief Scientist (OCS) serves as the agency's focus for scientific, medical, and related activities within OC.

C.2.1 Office of Counterterrorism and Emerging Threats

OCET Essential Employees

Assistant Commissioner for Counterterrorism and Emerging Threats

Deputy Director, OCET

Director, Medical Countermeasures Initiative Regulatory Policy

Senior Advisor for Influenza

Senior Program Manager, Office Emergency Response Coordinator

OCET works with FDA's medical product Centers to ensure the availability of medical countermeasures that can improve survival and mitigate and treat injuries from pandemic influenza. In addition to the functions outlined in the FDA EOP Base Plan, OCET coordinates and advises senior FDA officials on the portfolio of FDA influenza medical countermeasures through the FDA Pandemic Influenza Task Force. These include pandemic influenza vaccines, antiviral drugs, diagnostics, medical devices, and PPE such as facemasks and respirators.

C.3 OFFICE OF OPERATIONS

OO Essential Employees

Deputy Commissioner for Operations/Chief Operating Officer
 Director, Office of Equal Employment Opportunity and Diversity Management
 Director, Employee Resource and Information Center
 Director, Division of Technical Services
 Director, Office of Business Operations and Human Capital Programs
 Director, Division of Facilities Engineering and Mission Support Services
 Associate Director, Division of Planning Engineering and Space Management
 Associate Director, Division of Operations Management and Community Relations
 Director, Office of Human Resources
 Associate Director for Operations, Office of Human Resources
 Associate Director for Human Capital, Office of Human Resources
 Director, Client Services Division, Office of Human Resources
 Director, Workforce Relations Division, Office of Human Resources
 Director, OSO
 Safety and Occupational Health Manager

OO provides executive direction, leadership, coordination, and guidance for the day-to-day operations of FDA; manages overall budgets and resources; and oversees management and business activities agency-wide as well as OC. OO also ensures proper conduct of FDA's administrative and financial management activities.

OO will provide workforce guidance and support to FDA Offices and Centers during a pandemic influenza emergency so that the agency's essential functions can continue with a potentially reduced number of employees. OO performs the following essential functions to support FDA's response to an influenza pandemic:

- **Office of Business Services (OBS).** The Employee Resource and Information Center (ERIC) staff will provide critical support to FDA personnel, Offices, and Centers during a pandemic influenza emergency, including:
 - **Fleet Services:** Ensuring essential ground transportation/fleet is available and accessible to meet critical needs.
 - **Mail Services:** Ensuring critical mail pick-up and delivery.
 - **Call Center support** for critically needed administrative services.
- **Office of Facilities Engineering and Mission Support Services (OFEMS).** OFEMS will ensure FDA facilities are safe and available for FDA staff. Temporary facilities may be acquired if necessary. Flexibility should be built into current leases and/or custodial contracts to address cleaning and maintenance of facilities' needs in the event of an emergency and/or have adequate supplies on hand such that FDA employees can perform these types of activities themselves, such as:
 - Building, operations, and maintenance
 - Alterations to FDA space
 - Real estate management (leasing)

OO Response Activities

Alert Phase

- Interact with HHS as appropriate.
- Provide active internal planning for pandemic preparedness, including review and communication of OO's pandemic influenza emergency response plan (ERP) to OO employees, ensuring essential personnel are equipped with necessary requirements to complete essential functions from decentralized worksites.
- Conduct disaster response training and scenario walkthroughs.
- Work with other FDA components to ensure emergency plans are ready and tested.
- Coordinate training for agency staff regarding prevention (e.g., PPE, social distancing, hygiene) and emergency operating procedures.
- Provide information to staff on personal hygiene and prevention.
- Coordinate phone numbers and services with building leasers, property management vendors, and contractors to verify their plans during the pandemic phase (i.e., backup contract services).
- Ensure essential personnel are equipped with necessary equipment to work from alternative locations, if possible.
- Advise employees planning leave or travel to take laptop computers home.

OO Response Activities

Pandemic Phase

- Perform all interpandemic phase and alert phase activities as appropriate and if requested by HHS.
- To the extent possible, activate and implement OO pandemic influenza Continuity of Operations (COOP) Plan as appropriate.
- Serve as agency liaison to HHS in obtaining appropriate medical countermeasures such as vaccines, antivirals, and PPE for agency staff.
- Address the health and safety of staff, in particular essential staff, that may not have the option for teleworking by providing countermeasures through occupational health services if necessary.
- Manage coordination of timekeeping functions and liaise with the Rockville Human Resources Center (RHRC) and the Program Support Center [PSC] to ensure FDA employees continue to receive compensation.
- Ensure key vendors are paid for their services to prevent termination of essential services and supplies, potentially damaging the FDA pandemic response capability.
- Ensure the FDA building closures and reopenings are updated in ERIC and posted on FDA's intranet as circumstances warrant.
- Ensure well-being of staff, and particularly essential staff, personnel who may not have the option for teleworking.
- Ensure critical administrative functions are supported through the Call Center.



C.3.1 Office of Finance, Budget, and Acquisition

C.3.1.1 Office of Budget

OB Essential Employees	
	Director
	Deputy Director
	Financial Advisor
	Senior Analyst

In the event of pandemic influenza, FDA will likely need a supplemental budget request to support unforeseen expenses during this critical time. The Office of Budget (OB) will facilitate this process by working with senior management and Centers/Offices to identify resource needs, implementing the process to formulate the budget request, providing essential support during the review and clearance process, and responding to questions from congressional and other stakeholders.

Staffing needs will vary, based on the amount of information that OB will need to obtain and the level of analysis that is necessary. OB will likely be able to formulate a supplemental request with about three to four OB staff.

If OB is debilitated by the pandemic, it can either work with the budget analysts at HHS to assist in facilitating the supplemental budget request or use the FDA Center analysts (if available), some of whom have worked with OB in some capacity.

Because a supplemental budget request can have numerous variables and a supplemental request must be reviewed and cleared very quickly, it is difficult to provide expanded services without an additional level of investment. A supplemental budget request must be completed in its entirety.

In the event of an influenza pandemic, the budget liaison function is an essential activity to communicate budget needs and information. OB will facilitate that process by conducting outreach and coordinated communications, gathering information, and communicating with senior FDA management, Centers and Offices, HHS, Office of Management and Budget (OMB), and congressional staff.

Staffing needs will vary based on the situation; however, three to five OB analysts can facilitate the liaison process using several different channels. During an influenza pandemic, the basics of the budget liaison function can be done with OB at half the level of staffing.

Quality of work, timeframes, and milestones may slip as a result of reduced staffing. The quality and consistency control function will be important to support any budget proposals and budget information provided to others in FDA, the Administration, Congress, and stakeholders. OB will facilitate that process by using OB historical data repositories.

Staffing needs will vary based on the situation; however, the quality level of review will depend upon the number of available staff.

If OB is debilitated by an influenza pandemic, it will then work with some of the Center analysts to review budgetary documents for quality and consistency. OB can provide training to Center analysts on how it performs its quality and consistency functions, such as cross-checking budget documents and numbers.

OB Response Activities
Alert Phase

- Track pandemic influenza budget requests and appropriations.
- Respond to questions from Congress and stakeholders.
- Analyze the adequacy of the FDA budget to prepare for pandemic influenza.
- Align annual budget requests to meet pandemic influenza obligations.
- If necessary, develop and advance a supplemental budget request to support unforeseen expenses related to preparing for an influenza pandemic.

OB Response Activities
Pandemic Phase

- Perform all pandemic alert activities as appropriate.

C.3.1.2 Office of Acquisitions and Grants Services

OAGS Essential Employees
Director, OAGS Associate Director, OAGS Director, Division of Acquisition Support and Grants Director, Division of Acquisition Programs Director, Division of Acquisition Operations Director of Information Technology

The Office of Acquisitions and Grants Services (OAGS) will ensure appropriate support services and supplies are acquired to support the agency's response to the pandemic. These include, in priority order:

1. **Purchase Cards (P-cards) (formerly *International Merchant Purchase Authorization Card (IMPAC)*).** OAGS manages the program and serves as the central point of contact (POC) between FDA and the central bank. Program offices use P-cards to make micropurchases (less than \$3,000). In the event of an emergency, certain OAGS employees will also have P-cards with higher transaction limits.
2. **Simplified Acquisitions.** OAGS awards these through warranted contracting officers. The bulk of FDA's acquisitions are purchase orders. There are fewer statutory requirements associated with these than with contracts, which makes them easier and faster to award than contracts. In the event that the OAGS workforce is drastically reduced or it is impossible to come into the office (e.g., under quarantine, caring for sick a family member), simplified acquisitions should be awarded whenever possible. Although the limit for a simplified acquisition is generally \$100,000, this threshold may be raised to \$250,000 in the event that a contingency operation is declared by the President, the Secretary of Defense, or a designee. Additionally, commercial items worth up to \$5 million can be bought using simplified acquisition procedures. The absolute number of purchase orders will probably decrease or stay the same even if the simplified acquisition threshold is raised.
3. **Contracts.** OAGS contracting officers negotiate, award, and administer contracts. Whenever an acquisition exceeds the relevant simplified acquisition threshold, goods and services must be purchased using contracts. Contracts typically take longer than simplified acquisitions to award, but

there are procedures, such as limiting competition on the basis of unusual and compelling urgency, that can accelerate the process.

4. **Interagency Agreements (IAGs).** OAGS negotiates and is responsible for all administrative and business-related matters associated with IAGs between FDA and other Federal Agencies. In the event of severely reduced staffing, it is likely that agencies will need to leverage the resources of other offices. FDA may leverage the resources of other agencies (e.g., reaching out to other HHS OPDIVs to take over exceptionally critical FDA functions) if FDA's staff is too small to handle them independently. OAGS will ensure it has sufficient staff with the knowledge to execute and administer IAGs.
5. **Grants.** OAGS administers FDA's grant program. In the event of an emergency, grants may be awarded for research or education activities that support FDA's pandemic influenza response work.
6. **Technology Transfer.** Technology transfer encourages partnerships for collaborative research. This strengthens FDA's research efforts and increases resources for mission-related projects. In the event of a pandemic, this is less of a priority than ensuring that mission-critical programs have the supplies they need.

C.3.1.3 Office of Financial Operations

C.3.1.3.1 Office of Financial Management

OFM Essential Employees
Director, OFM
Business Continuity Coordinator (Ancillary Duty)
Division Director, Financial Support Services
Division Director, Budget Execution
Division Director, Accounting
Division Director, Business Transformation, Administration and Management

C.3.2 Office of Information Management

OIM Essential Employees
Chief Information Officer
Deputy Chief Information Officer
Director of Division of Business Partnership and Support
Deputy Director of Division of Business Partnership and Support
Director of Division of Chief Information Officer Support
Deputy Director of Division of Chief Information Officer Support
Director of Division of Infrastructure
Deputy Director of Division of Infrastructure
Director of Division of Systems
Deputy Director of Division of Systems
Director of Division of Technology
Deputy Director of Division of Technology

OIM enables FDA's strategic efforts to transform and improve IT systems and infrastructure needed to support critical agency operations. OIM performs the following essential functions to support FDA's response to an influenza pandemic:

- Implementing and enhancing common IT systems to support FDA's response to an influenza pandemic.

- Maximizing the availability and use of IT that increases electronic access for the public, as well as the full span of FDA's other external (e.g., public consumers, industry, Government, academic) and internal customer bases, while maintaining effective security.
- Aligning IT investments to agency pandemic influenza response work.
- Consolidating, modernizing, and optimizing FDA's IT infrastructure to strengthen its pandemic influenza response work.
- Providing the platform required for FDA to meet agency-wide IT initiatives for pandemic influenza response.

OIM Response Activities
Alert Phase and Pandemic Phase

During an influenza alert and pandemic phases, OIM tactical activities will include:

- **Command and Control of Reporting Offices.** OIM will define and manage the emergency while ensuring the operations of the Center and Office are maintained as required (Levels 1 to 3) and essential functions are maintained (Level 4).
- **Computer Room Facilities.** OIM will ensure the computer room facilities function and will coordinate with PSC and building management. If cooling, generator, and power services are not available to the Parklawn Data Center, then all IT resources in the data center are also not available.
- **IT Security Services.** OIM will ensure IT security services are available that are essential to protect FDA's IT assets. Increased attacks on FDA's IT resources are likely during a perceived time of weakness. Personnel will focus their efforts on security measures, such as firewall connectivity and others, ensuring that security controls for hardware, software, and telecommunications are effective and protect privacy, confidentiality, and availability of FDA data. Personnel will monitor firewall, intrusion detection, anti-malware, and security controls for critical and high-impact FDA systems, providing incident response of those potential issues that would have a severe impact on FDA operations. These services are dependent on the computer room facilities.
- **LANs and Wide Area Networks (WANs).** OIM will ensure the availability of LANs/WANs that will be critical for both field and local users to access agency IT resources. Demand may be reduced due to fewer numbers of employees in the office. This service is dependent on the computer room facilities and IT security services. Network teams will focus their support efforts on those buildings declared operational and will not monitor or respond to network failures in buildings that are unoccupied. Networking resources can be leveraged between the Network Control Center and the LAN team.
- **Internet Services.** OIM will maintain Internet services that are critical to the agency's ability to communicate with regulated industry and provide access to FDA's internal and external IT resources. The demand for these services will be greater because most staff will revert to accessing these resources remotely through the Internet. Services are dependent on outside vendors and the users' local Internet service provider (ISP). Networking resources can be leveraged between the Network Control Center and the LAN team. If additional bandwidth is needed, the agency will request that the ISP increase bandwidth. During a pandemic event, any reengineering of the network and service segments will cease so that efforts are focused on supporting this service.
- **Active Directory.** OIM will ensure Active Directory availability as it provides authentication services when users log on to the FDA systems. Although the demand for this service may not be

great, access to IT systems will not occur if this application is down. Active Directory is dependent on computer room facilities, IT security services, LAN/WAN, and Internet services.

- **Telephone.** OIM will ensure telephone availability, which is a critical need. It is estimated that voice and video services will increase. Within Government facilities, usage will increase substantially with the possibility of employees being ill and more working from home during a pandemic phase. This service is dependent on computer room facilities; IT security services; LAN/WAN networks; Internet services; local exchange carriers; Verizon; and the National Institutes of Health (NIH), which manage the Parklawn voice switch. This function is covered by two groups that manage Integrated System Digital Network (ISDN) and Voice over Internet Protocol (VoIP).
- **Email/BlackBerry Services.** OIM will ensure COOP for FDA email and BlackBerry services. In addition to the growing demand for email and BlackBerry services, coordination of both services is critical because each service backs the other. As of October 2009, the FDA email system is no longer operated by HHS. This change will allow OIM to improve service and COOP for both email and BlackBerry services. In the event of an email failure, expert support will troubleshoot and resolve outages. In addition to communications being sent out through email and BlackBerry services, alternate communication avenues will be used, including the FDA Internet, intranet, and recorded announcements at ERIC, to ensure necessary information is communicated to employees. These alternate communication vehicles are dependent on computer room facilities (Parklawn Data Center), IT security services, LAN/WAN, Internet services, local exchange carriers, Verizon, NIH (which manages the Parklawn voice switch), and BlackBerry Personal Identification Number (PIN)-to-PIN services. There may be a need to have an adequate supply of additional BlackBerry devices to distribute to essential personnel during an influenza pandemic.
- **Outlook Web Access (OWA).** OIM will monitor the availability of OWA, since this is another method of accessing FDA email from non-FDA-issued computers that have access to the Internet. In order to use OWA, users will need their Remote Secure Access (RSA) SecureID token. OWA gives FDA employees greater freedom to access their email from most personally owned or public-access personal computers (PCs) because it does not require that the computer be FDA-issued or that a connection be made to the FDA network.
- **Help Desk Services.** OIM will manage and maintain Help Desk services where demand is expected to increase substantially as the agency executes its response plans. Although most problems may be resolved remotely, there will be fewer onsite Help Desk technicians available for support within FDA buildings. There will also be a great demand from remote logon users who have not logged into the systems in more than 6 months. An estimated 1:200 person ratio will be needed to service users. These services are dependent on building closures, numbers of users who are working in the office, and numbers who are working from home or other alternate worksites.
- **Secure Remote Access System (SRAS) Infrastructure.** OIM will ensure a SRAS infrastructure that will support 3,000 concurrent broadband users and about 350 dial-in users, although these numbers will increase as funding is increased. Once an order is given to shelter at home, there will be a very high demand for SRAS and, consequently, a likely surge overcapacity for dial-in service and considerable stress on broadband bandwidth. Dial-in service is not the recommended method of remote access due to the slow performance associated with this connection. This service is dependent on all essential IT infrastructure components being online, the users' local ISP, and the telephone company having enough capacity to support the demand.
- **Storage Management.** There are many FDA applications that will need access to data storage devices. OIM staff may have limited capabilities to respond to all demands. A prioritized list of all applications will need to be derived to ensure adequate support of key applications.

- **Application Services.** Users will have to access FDA applications during a pandemic outbreak. OIM staff may have limited capabilities to respond to all of the demands. A prioritized list of all applications will need to be derived to ensure adequate support resources are available. Support for this service will be dependent on the number of critical applications needed to support a response to a pandemic outbreak. Once those applications are determined, a support plan will be published that identifies the servers and storage devices that will need support. Additionally, there are other applications, although not directly supporting a pandemic outbreak, that will need to be supported, such as the Prior Notice System. These services are dependent on all critical IT resources being operational. Because the www.fda.gov website is hosted externally, OIM will need to coordinate with the vendor to ensure continuity of service.
- **File/Print Services.** File and print services are dependent on accessibility to the network drive and will be dependent on all critical IT resources being operational. OIM will work diligently to ensure all network drives and printers are accessible. However, there may be times, such as during a scheduled or emergency maintenance outage, that certain network drives and printers will not be available. To ensure employees have access to files and documents necessary to carry out their duties at all times, OIM explores secure technologies, such as the IronKey device, that will allow employees to save and retrieve documents and files securely to and from an external drive.
- **Communication Services.** OIM will continue communication services that are essential for overall information dissemination as well as for technical and project management during a pandemic influenza event. Technical IT operations information, currently issued through the OIM News and Flash accounts, will continue to provide information on status and outages to users. OIM can leverage the other communication officers in OO. Announcements via email are dependent on HHSMail services.
- **Contracts/Procurements Coverage.** OIM will ensure coverage for contracts/procurements that are essential, as there may be a need to procure additional contract services or hardware/software components. This function, although important, may be performed by another OM component. This service is dependent on the availability of OAGS and key OIM staff. OIM can leverage other organizations to handle agency procurement needs.
- **Critical Patch Management.** Patches reduce or correct IT security threats or system problems. All efforts will be made to identify and apply patches that will address the most critical security vulnerabilities. All others will be prioritized and applied at the earliest convenience. This service is dependent on test servers and the availability of the network and server teams to load the patches.

C.4 OFFICE OF FOODS AND VETERINARY MEDICINE

Office of Foods Essential Employees
Deputy Commissioner for Foods Associate Commissioner for Food Protection Chief Medical Officer and Director of Outbreaks Senior Advisor to Director of Outbreaks

C.4.1 Coordinated Outbreak Response and Evaluation

CORE Essential Employees
FDA Liaison to the CDC Prevention Manager Response Manager

The Coordinated Outbreak Response and Evaluation (CORE) Network is responsible for managing food-borne outbreak surveillance, response, and post-response activities related to incidents involving multiple illnesses in the United States linked to FDA-regulated human and animal food and cosmetic products. During an influenza pandemic, the FDA liaison is responsible for working with the CDC for outbreak surveillance that may involve human or animal food. CORE as a multidisciplinary team may provide subject matter expertise, as needed, to the Centers. CORE would not coordinate or manage FDA's response. If the agency activates the FDA EOC, CORE may provide resources, to the extent possible, to support the agency's incident management response.

C.4.2 Center for Food Safety and Applied Nutrition

CFSAN Essential Employees
Center Director Deputy Directors Director, Office of Management Systems Director, Office of Food Defense Communication and Emergency Response Office Directors CFSAN COOP Leader

The Center for Food Safety and Applied Nutrition (CFSAN), in conjunction with the agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the Nation's food supply is safe, sanitary, wholesome, and honestly labeled and that cosmetic products are safe and labeled properly. CFSAN has the authority to regulate establishments that manufacture, process, pack, hold, or grow food involved in interstate commerce, including manufacturers, distributors, and warehouses. It also determines whether data collected by another agency or organization are adequate for FDA decisions regarding food and cosmetic issues in an emergency. CFSAN performs the following essential functions to support FDA's response to an influenza pandemic:

- Develop and evaluate analytical methods for identifying influenza virus in foods.
- Prohibit the extra-label use of influenza antiviral drug products in animals when such use presents a risk to the public health.

CFSAN Response Activities

Alert Phase

- Develop and evaluate analytical methods for identifying influenza in food.
- Identify foods and feeds that are at elevated risk of contamination and investigate the effectiveness of food and feed processing and preparation practices for inactivating influenza viruses.
- Develop and disseminate recommendations on measures to prevent the spread of influenza virus via FDA-regulated foods.
- Activate internal planning for pandemic preparedness, including the establishment of a pandemic influenza ERP (i.e., identifying essential functions, identifying essential personnel with adequate tiers for redundancy, and equipping essential personnel with necessary requirements to complete essential functions from decentralized worksites).
- Coordinate food and feed safety activities and plans with Federal and State agencies, industry, and others.
- Food safety activities, including surveillance, inspections, and monitoring.
- Disseminate accurate information about food safety emergencies, which is vital to minimize the adverse impacts of threats or public health emergencies.

CFSAN Response Activities

Pandemic Phase

Perform all pandemic alert activities as appropriate and if requested by HHS and the Homeland Security Council (HSC):

- To the extent possible, activate and implement the CFSAN ERP as appropriate.
- Inventory human capital and determine the well-being of staff.
- Focus the Center's remaining workforce on issues related to products associated with the ongoing situation; significant focus on ensuring food security, safety, and defense.
- Conduct outreach to the public, industry, foreign public health authorities, and other stakeholders regarding food safety.
- Provide cadre of trained CFSAN personnel for rapid deployment to the FDA EOC, to HHS, and to external organizations to provide support for contingency functions.

C.4.3 Center for Veterinary Medicine

CVM Essential Employees
Center Director
Executive Director
Senior Advisor for Science
Associate Director for Policy and Executive Programs
Senior Policy Analyst and Director, CVM Executive Secretariat
Director, CVM Communications Staff
Executive Officer and Director, OM
Director, Office of Surveillance and Compliance
Director, Division of Animal Feeds
Director, Division of Compliance
Director, Office of Research
Director, Office of New Animal Drug Evaluation

The Center for Veterinary Medicine (CVM) ensures the safety, efficacy, and quality of drugs for animals, including food-producing and companion animals, animal food and feed, and medical devices used on animals potentially threatened by an influenza outbreak. CVM performs the following essential functions to support FDA's response to an influenza pandemic:

- Maintaining essential international program activities.
- Collaborating with public health agencies (e.g., CDC, HHS, and the U.S. Department of Agriculture [USDA]) regarding feed contaminant, tissue residue programs, and other monitoring programs for meat and poultry involved in influenza outbreaks.
- Providing advice in the assessment of animal drug or feed product possibly affected by influenza.
- Providing advice to pet owners regarding animal safety measures related to influenza.

CVM Response Activities

- Coordinate food and feed safety activities and plans with Federal and State agencies, industry, and others.
- Identify foods and animal feeds that are at elevated risk of contamination and investigate the effectiveness of food and feed processing and preparation practices for inactivating influenza viruses.
- Prohibit the extra-label use of influenza antiviral drug products in animals when such use presents a risk to the public health.
- Manage CVM laboratory capabilities and provide this information to the FDA EOC.
- Develop and disseminate recommendations on measures to prevent the spread of influenza virus via FDA-regulated foods and animal feeds.

CVM Response Activities
Pandemic Phase

- Perform all pandemic alert activities as appropriate.

C.5 OFFICE OF MEDICAL PRODUCTS AND TOBACCO

C.5.1 Office of Special Medical Programs

OSMP Essential Employees
Associate Commissioner Special Medical Programs

C.5.1.1 Office of Combination Products

OCP Essential Employees
Director
General Attorney (2)
Biologist (2)

The Office of Combination Products (OCP) ensures the prompt assignment of combination products to FDA Centers, the timely and effective premarket review of such products, and consistent and appropriate post-market regulation of like products subject to the same statutory requirements to the extent permitted by law. OCP performs the same functions mentioned in the FDA EOP to support FDA's response to an influenza pandemic.

C.5.2 Center for Drug Evaluation and Research

CDER Essential Employees
Center Director
Deputy Director
Director, Office of Regulatory Policy
Director, Office of Communications
Director, Office of Planning and Informatics
Director, Office of Counterterrorism and Emergency Coordination
Director, Office of Compliance
Director, Office of Pharmaceutical Science
Director, Office of Surveillance and Epidemiology
Director, Office of Translational Sciences
Director, Office of New Drugs
Deputy Director, Office of New Drugs
Director, Office of Antimicrobial Products
Associate Director, CDER Drug Shortage Program
Director, Office of Management

The Center for Drug Evaluation and Research (CDER) ensures the safety, efficacy, and quality of drugs and therapeutic biologic agents for use as medical countermeasures in response to outbreaks of influenza virus. CDER performs the following essential functions to support FDA's response to an influenza pandemic.

CDER Response Activities
Alert Phase

- Perform drug approval activities (i.e., review of investigational and new drug applications, associated labeling, and advertising and guidance for field inspections).



- Perform drug safety activities, including adverse event monitoring, drug product quality activities, and post-market surveillance.
- Perform compliance activities, including regulatory surveillance assessments and actions and coordination of actions involving recalls, shortages, tampering, fraudulent or counterfeit products, and inspections.
- Perform emergency response coordination/activities for all CDER-regulated products, liaison to the Strategic National Stockpile (SNS), maintenance of the CDER Situation Room (CSR), program responsibility for classified documents and security clearances, and coordination of EUAs.
- Monitor for drug shortages.
- Facilitate communication with manufacturers of pandemic influenza products on issues of availability, adverse event reporting, and potential new products.
- Collaborate with HHS regarding stockpile issues, including labeling, appropriate usage, shelf-life and expired product considerations, product performance, pharmacovigilance and monitoring, use in special populations, and other evolving issues.
- Process pre-EUAs in anticipation of declared emergencies.
- Activate internal planning for pandemic preparedness, including the establishment of a Continuity of Business Operations Plan (COBOP); identifying essential functions and essential personnel with adequate tiers for redundancy; and equipping essential personnel with necessary equipment/procedures to complete essential functions from decentralized worksites.

CDER Response Activities

Pandemic Phase

- Continue to perform drug approval activities (i.e., review of investigational and new drug applications, associated labeling, and advertising and guidance for field inspections).
- Perform all interpandemic phase and pandemic alert activities as appropriate and if requested by HHS and the HSC.
- To the extent possible, activate and implement the CDER COBOP, CDER Pandemic Administrative Operating Plan, and other ERPs as appropriate.
- Inventory human capital and the capability of staff to work.
- Focus the Center's remaining workforce on issues related to products associated with the ongoing situation, significant life-saving products, and new generic drugs to prevent shortages and respond to significant adverse event incidents, EUA requests, and emergency response coordination issues.
- Conduct public outreach to industry, foreign public health authorities, the public, and other stakeholders regarding antiviral drugs.

C.4.3 Center for Biologics Evaluation and Research

CBER Essential Employees	
	Center Director
	Deputy Director
	Associate Directors
	Emergency Operations Coordinator
	International Affairs Advisor
	Program Manager for Pandemic Influenza
	Senior Advisor for Counterterrorism/Medical Countermeasures
	Director, OM
	Director, Office of Vaccine Research and Review
	Director, Office of Blood Research and Review
	Director, Office of Compliance and Biologics Quality
	Director, Office of Communications, Outreach, and Development
	Director, Office of Biostatistics and Epidemiology
	Director, Office of Cellular, Tissue, and Gene Therapies
	CBER Office of Information Management Liaison

The Center for Biologics Evaluation and Research (CBER) ensures the safety, efficacy, and quality of biological products potentially used as medical countermeasures during a pandemic influenza emergency. CBER performs the following essential functions to support FDA's response to an influenza pandemic.

CBER Response Activities
Alert Phase

- Participate, through the WHO Global Influenza Surveillance and Response System (GISRS) (formerly known as the Global Influenza Surveillance Network or GISN), to obtain, identify, and characterize influenza wild-type (wt) viruses of pandemic potential.
- Work with WHO Collaborating Centres (CCs) and WHO Essential Regulatory Laboratories (ERLs) to generate, calibrate, and cross-calibrate reference reagents for vaccine formulation as necessary.
- Continue internal capacity building efforts, including development of novel reassortants (animal H1, H2, H5, H7, H9, etc.) suitable for vaccine production, methods development to improve assays for clinical assessment, and assays necessary for product release.
- Provide guidance to sponsors regarding new and/or advanced product development and clinical trials research, including novel vaccines and therapies.
- Conduct post-marketing surveillance and enforcement activities relating to biological products in accordance with pandemic guidance as appropriate.
- Industry outreach for purposes of increasing vaccine production and fill/finish capacity to meet pandemic demand.
- Provide CBER management that will carefully examine all domestic and foreign travel to restrict if necessary.
- Collaborate with HHS, other parts of the USG, and other international organizations, such as WHO, on the framework and method for appropriate selection of pandemic reference strains for vaccine production.



- Collaborate with HHS regarding stockpile issues, including labeling, appropriate usage, shelf-life considerations, product performance, pharmacovigilance and monitoring, use in special populations, and other evolving issues.
- Provide active internal planning for pandemic preparedness, including the establishment of a pandemic influenza ERP and continual updates as needed, identifying essential functions and essential personnel with adequate tiers for redundancy, and equipping essential personnel with necessary requirements to complete essential functions from decentralized worksites.
- To the extent possible, assess the availability of biological products and take steps to divert or mitigate the impact of shortages.
- Provide training to staff regarding prevention (e.g., PPE, social distancing, hygiene) and emergency operating procedures.
- Play an integral part in any global harmonization of regulatory processes within FDA's existing framework for pandemic activities, should this be necessary.

CBER Response Activities

Pandemic Phase

- Engage in pandemic activities as appropriate and if requested by HHS and the HSC.
- To the extent possible, activate and implement the CBER Pandemic Influenza COOP Plan and other ERPs as appropriate.
- To the extent possible, ensure well-being of staff and, particularly, essential staff personnel who may not have the option for teleworking (such as those involved in laboratory work supporting vaccine production, quality control, and release) by the provision of countermeasures through occupational health services in coordination with OC's OM.
- Respond to and process EUA requests after a declaration of public health emergency by the HHS Office of the Secretary.
- Using a risk-based approach, prioritize allocation of review and inspectional resources for licensure and emergency use of medical countermeasures, as well as other essential activities that will confer the maximum and most beneficial public health impact.
- Ensure timely information flow within CBER, as well as other organizations within the USG.
- Facilitate dialogue and information exchange with industry and international entities, as well as participation in global efforts to develop consensus approaches, to the extent possible, for clinical trial designs and adverse event reporting that can guide vaccination strategies.
- Conduct public outreach to domestic and foreign public health authorities, the public, and other stakeholders regarding pandemic vaccines and other biological products.

C.5.4 Center for Devices and Radiological Health

CDRH Essential Employees	
Center Director	
Deputy Director	
Senior Associate Director	
Director, Office of Management Operations	
Office Director, Office of Device Evaluation	
Office Director, Office of In-Vitro Diagnostic Device Evaluation and Safety	
Office Director, Office of Compliance	
CDRH COOP Leader	
Division Director, Division of Anesthesia General Hospital Infection Control and Dental Devices	
Office Director, Office of Surveillance and Biometrics	
Office Director, Office of Communication, Education, and Radiation Programs	

CDRH ensures the safety, efficacy, and quality of medical devices used during a pandemic influenza emergency. CDRH performs the following essential functions to support FDA's response to an influenza pandemic.

CDRH Response Activities
Alert Phase

- Educate device users on how to use influenza-related devices safely and effectively.
- Communicate influenza-related device activities and information to industry and consumers.
- Process pre-EUAs in anticipation of declared emergencies.
- Facilitate device development, regulatory review, and production of devices that may be needed during an influenza pandemic.
- Conduct post-market surveillance to monitor the safety and effectiveness of influenza-related devices (including devices used for diagnosis, devices used to administer therapeutics, PPE, and devices used for supportive care).
- Lend technical expertise and assistance to international efforts to prepare for a potential influenza pandemic.
- Support efforts to ensure an adequate supply of influenza-related devices through cooperative interactions with manufacturers and distributors and coordination with the SNS to determine the adequacy of stocks and actions required to meet targeted amounts.
- Use an emergency shortages database to identify and monitor needed supplies.
- Collaborate with public health agencies regarding product stockpile issues, appropriate usage, labeling, product performance, monitoring, use in special populations, and other evolving issues.
- Collaborate with HHS regarding stockpile issues related to medical devices.
- Activate internal plans for pandemic preparedness in regard to staff communication and readiness, including teleworking during the pandemic.
- Provide training for staff on prevention and protection techniques for the influenza pandemic that must be followed in the workplace.

**CDRH Response Activities****Pandemic Phase**

- Perform all pandemic alert activities as appropriate.
- Process EUAs for products after a declaration of public health emergency by the HHS Office of the Secretary.
- Conduct post-market surveillance to monitor the safety and effectiveness of influenza-related devices (including devices used for diagnosis, devices used to administer therapeutics, PPE, and devices used for supportive care).
- Support efforts to ensure an adequate supply of influenza-related devices through cooperative interactions with manufacturers and distributors and coordination with the SNS to determine the adequacy of stocks and actions required to meet targeted amounts.
- Use an emergency shortages database to identify and monitor supplies of certain devices that have the potential to be in demand, but in short supply during influenza outbreaks.

C.6 OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

C.6.1 Office of International Programs

OIP Essential Employees

Deputy Commissioner for International Programs
Associate Commissioner for International Programs
Deputy Director, OIP

OIP is responsible for coordinating and, if appropriate and permitted, communicating appropriate emergency-related information to foreign governments and international organizations, such as WHO. OIP also receives information and requests for information (RFIs) from foreign governments. OIP performs the following essential functions to support FDA's response to an influenza pandemic:

- Maintain contacts and efficient channels for communications with FDA counterpart agencies and FDA staff in other countries to assess the impact of the pandemic on FDA and advise on appropriate actions.
- Monitor and report on relevant international development and resources.

OIP Response Activities

Alert Phase

- Exchange information with foreign counterparts to ensure compliance with FDA laws, regulations, and policies and consistency in responses to an influenza pandemic.
- Monitor and report on relevant international developments and resources.
- Coordinate and advise on international technical cooperation, assistance, and capacity-building activities.
- Establish policies and procedures pertaining to international travel and processing international travel requests.

OIP Response Activities

Pandemic Phase

- Conduct international pandemic alert activities.
- Follow the Pandemic Influenza Annex to the FDA EOP and other relevant advice.
- If staff is limited, OIP functions will be restricted to:
 - Communicating with foreign governments and international organizations, including foreign embassies and consulates in the United States.
 - Exchanging information with foreign counterparts to ensure compliance with FDA laws, regulations, and policies and consistency in responses.
 - Implementing policies and procedures pertaining to international travel and processing international travel requests; OIP will process only international travel that is consistent with requirements and limitations pertaining to the pandemic situation.

C.6.2 Office of Regulatory Affairs

ORA Essential Employees	
Associate Commissioner for Regulatory Affairs Deputy Associate Commissioner for Regulatory Affairs Senior Advisor Office Director Division Director Regional Food and Drug Director or equivalent District Director Laboratory Director Director of Investigations Branch Director of Compliance Branch Compliance Officer/Import Compliance Officer Legal Instrument Examiner Administrative Officer Supervisory Consumer Safety Officer Deputy Regional Food and Drug Director Emergency Response Coordinator Laboratory Supervisor Special Assistant to District Director Commissioned Corps Officers Special Agent in Charge (SAIC), Office of Criminal Investigations (OCI) Headquarters/ Investigative Operations Division SAIC OCI Headquarters/Administrative Operations Division SAIC OCI Office of Internal Affairs Senior Operations Manager, OCI/Headquarters COOP Coordinator	Director of Import Operations Branch Investigator/Consumer Safety Officer Criminal Investigator/Special Agent Consumer Complaint Coordinator Recall Coordinator Director of Cooperative Programs Regional Specialists/Cooperative Programs (Milk, Shellfish, Retail, Radiological Health) Laboratory Analyst Laboratory Branch Director Industrial Hygienist Staff Assistants National Health Fraud Coordinator Public Information Branch Representative/Manager Director, Headquarters/ OCI Public Affairs Specialist Program Support (<i>as needed for response</i>) Timekeeper Sample Custodian

ORA, led by the Associate Commissioner for Regulatory Affairs (ACRA), protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products. ORA is the lead office for all agency field activities. ORA maintains a database of FDA-regulated establishments that enables FDA to rapidly identify establishments adversely affected by a pandemic influenza incident. In the event of product shortages, ORA's establishment database can assist the agency in identifying firms with needed production capabilities or product inventory. ORA performs the following essential functions to support FDA's response to an influenza pandemic:

- Investigating and pursuing enforcement action against fraudulent or counterfeit pandemic influenza products.
- Initiating surveillance and follow-up activities for fraudulent pandemic products sold over the Internet.
- Conducting post-market surveillance activities related to vaccines (team biologics).

ORA Response Activities

Alert Phase

- Conduct domestic and foreign inspections; import entry review, field exams, sample collections, and analyses; and take appropriate enforcement actions against violative firms or products of heightened concern because of their relation to pandemic influenza (for instance, vaccines and influenza drugs) to ensure compliance with applicable regulations.
- Investigate and pursue enforcement action against fraudulent or counterfeit pandemic influenza products, both domestic and foreign.
- Provide incident command training to essential staff and other staff involved in emergency response activities.
- Participate in internal FDA and external pandemic influenza emergency exercises, including pandemic influenza.
- Ensure staff members have equipment and supplies needed in order to work from home.
- Participate in educational outreach activities for industry, FDA regulatory counterparts, and other external customers.
- ORA management to carefully examine all foreign travel and restrict if necessary.
- Maintain situational awareness of pandemic influenza cases worldwide through OCM.
- Activate internal ORA planning for pandemic preparedness, including the establishment of a pandemic influenza ERP; identify essential functions and essential personnel with adequate tiers for redundancy; and equip essential personnel with necessary equipment to complete essential functions for decentralized worksites.

ORA Response Activities

Pandemic Phase

- All activities stated above also apply during an alert phase, as appropriate, and if requested by HHS and the HSC.
- Intensify efforts to identify fraudulent, harmful, or ineffective products that are promoted for preventing, diagnosing, or treating pandemic influenza.
- Give priority attention to pandemic influenza-related work and life-threatening/sustaining work associated with emergency response coordination activities.
- To the extent possible, activate and implement the pandemic influenza ERP, COOP Plan, and other ERPs as appropriate.

C.6.2.1 Office of Regulatory Affairs Laboratories

ORA laboratories will provide analytical support for agency efforts to identify counterfeit or fraudulent pandemic influenza products and to support their removal from the marketplace. ORA laboratories will also participate in shelf-life extension and related programs associated with the maintenance of national stockpiles of critical influenza products.

D. DIRECTION, CONTROL, AND COORDINATION

This section provides a description of Incident Command System (ICS) positions and groups, which are specific to a pandemic influenza response and describes their primary roles and responsibilities.

FDA response operations for major incidents, such as pandemic influenza, are based on the concepts, practices, and principles of NIMS and its organizational structure, the ICS. Among other things, NIMS prescribes what types of information FDA should provide the HHS SOC and in what format, including SitReps and Incident Action Plans (IAPs). NIMS also requires the use of universal terminology to ensure a common understanding of requirements and requests in an interagency environment. The ICS organizational structure provides standard nomenclatures for both teams and individual positions. *For a complete listing of the FDA ICS structure (IMG)³ refer to FDA EOP, Section D, “Direction, Control, and Coordination.”*

Expansions of the FDA response structure for a pandemic influenza response may vary according to numerous considerations and operational factors. ICS offers flexibility in determining the right structural approach for the specific circumstances of the incident at hand. Dependent on the incident objectives established and strategies developed, the IMG may include Logistics and Finance/Administrative as part of the response and expand FDA’s command structure Operations Section, including any one of the groups described in Section D below (see **Figure D-1**).

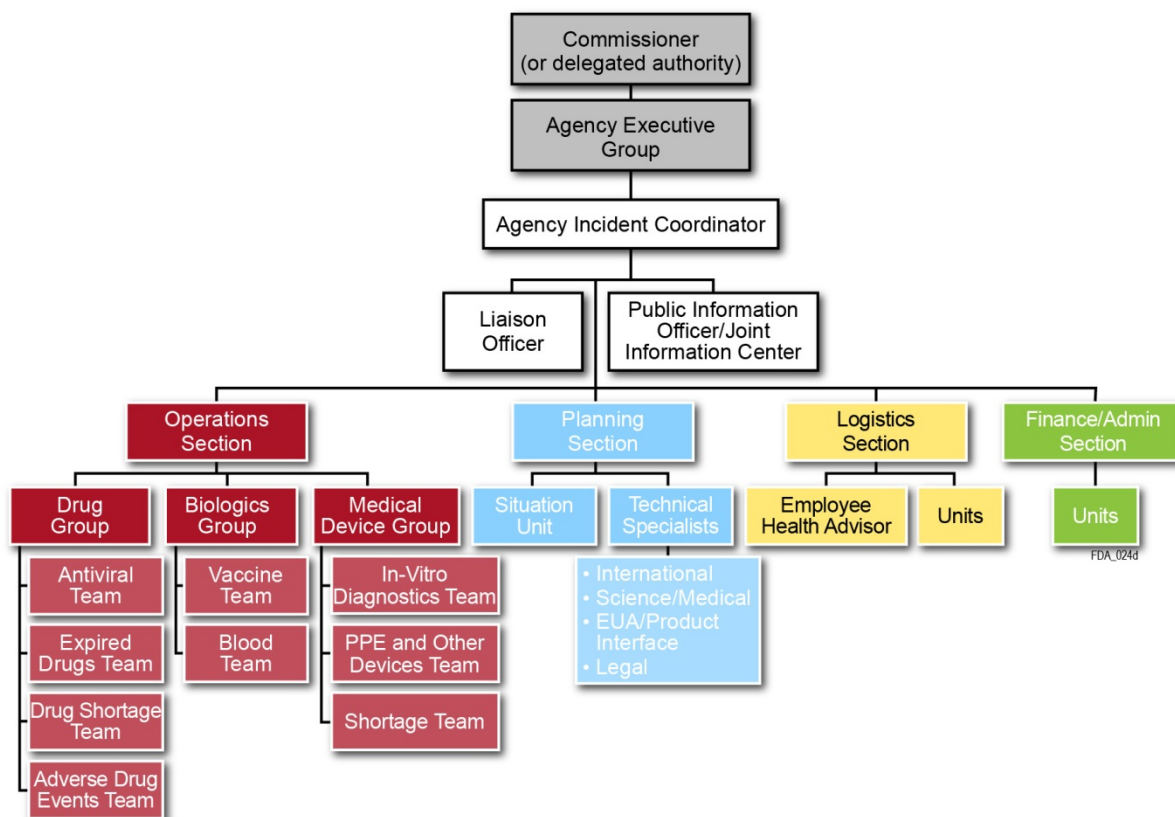


Figure D-1. Possible Pandemic Influenza IMG Structure

³ For more information on specific roles and responsibilities of each ICS position, refer to the *FDA Incident Management Handbook*.

D.1 COMMAND STAFF

The FDA Command Staff includes a Public Information Officer (PIO) and Liaison Officers (LNOs). Technical Advisors may be assigned to the Planning Section or to the Command Staff working directly for the Agency Incident Coordinator (AIC). Technical Advisors can include the Science/Medical Advisor, EUA/Product Interface Advisor, International Advisor, and Legal Advisor.⁴

D.1.1 *Pandemic Influenza-Specific Liaisons*

When activated, the FDA EOC serves as the agency-wide focal point for pandemic influenza emergency operations, coordination, and communications. External liaisons from the CDC or other agencies may be present at the FDA EOC. FDA may also send liaisons to the coordinating agency for the event or participate in the response coordination if an incident or unified command is set up.

D.1.2 *Legal Advisor*

D.1.2.1 *Legal Group*

The Legal Group works to address the following issues related to pandemic influenza in support of the Legal Advisor:

- Adverse event reporting guidance.
- Fraudulent products warning letters and enforcement actions.
- FDA-regulated products used during an influenza pandemic (i.e., export and import, overriding patents, and public informational statements).
- EUAs.
- Occupational issues (e.g., agency recommendations for employees, ensuring harmonization of multiple guidance for employees provided by multiple entities).
- Preparation for congressional hearings.

D.2 GENERAL STAFF

The General Staff is responsible for the functional aspects of the FDA ICS. The General Staff consists of the Operations, Planning, Logistics, and Finance/Administration Sections, which comprise designated FDA headquarters and field emergency staffs. Individual position assignments within these Sections are discussed in the FDA EOP.

D.2.1 *Operations Section*

The Operations Section is responsible for coordinating all agency activities related to regulated products in response to an influenza pandemic event. **Figure D-1** depicts FDA's Operations Section during a pandemic influenza response. The groups listed below could possibly be established when the number of resources exceeds the manageable span of control of the IMG and the Operations Section Chief. Groups are established to divide the incident into functional areas of operation. Additional levels of supervision may also exist below the Group level.

⁴ See the FDA EOP, Section D, for a description of the Technical Advisor positions.

D.2.1.1 Drug Group

The Drug Group addresses drug issues, such as adverse event reporting, labeling changes, whether EUAs for drugs are appropriate, and what restrictions should be placed on uses authorized under EUAs related to an influenza pandemic operational response. The following are some potential teams, led by CDER staff, that may be needed to manage mitigation and recovery issues.

D.2.1.1.1 Antiviral Team

The Antiviral Team addresses issues concerning the availability of antiviral drugs and EUA requests and manages adverse event reporting and monitoring.

D.2.1.1.2 Expired Drugs Team

The Expired Drugs Team deals with such issues as use of expired antiviral drugs and drugs out of specification, including those in the SNS. This team would have input in discussing whether an EUA should/can include private sector stockpiles (e.g., hospital associations, large employers) or whether a separate authorization is needed. The Expired Drugs Team would also monitor labeling and Shelf Life Extension Program (SLEP) issues related to the event.

D.2.1.1.3 Drug Shortage Team

The Drug Shortage Team is responsible for reporting on the availability and surge capacity for antiviral drugs, monitoring commercial inventory, and working with manufacturers of influenza drug products to prepare for possible increases in demand. The team would contact intravenous antibiotics, intravenous fluid manufacturers, and other critical care drug manufacturers to prepare for possible increased needs.

D.2.1.1.4 Adverse Drug Events Team

The Adverse Drug Events Team assists with the monitoring of adverse drug events specifically to identify undesired side effects and unexpected adverse effects from a drug product used to treat influenza.

D.2.1.2 Biologics Group

The Biologics Group addresses vaccines, blood, and other biologics issues as part of an influenza pandemic operational response. Some potential teams, with team leaders from CBER staff, may be needed to manage mitigation and recovery issues.

D.2.1.2.1 Vaccine Team

The Vaccine Team works with U.S.-licensed manufacturers of influenza vaccines concerning the regulatory and scientific aspects of the development and licensure of vaccines for the novel influenza virus. They participate in various recurring meetings facilitated by the Biomedical Advanced Research and Development Authority (BARDA), National Vaccine Program Office (NVPO), CDC, WHO, and international regulators, such as the European Medicines Agency (EMA) and Health Canada.

In addition, the Vaccine Team works to address any issues related to:

- Preparation of reference strains from which manufacturers can make viral seeds for vaccine production.
- Production of reagents to test vaccine potency.
- Providing strains for assays and manufacture as necessary.
- Standardization of clinical trials.
- Vaccine production.

- Discussion with manufacturers, when needed, regarding the information needed to potentially support the use of unapproved vaccines in a declared emergency under an EUA.

D.2.1.2.2 Blood Team

The Blood Team is responsible for providing guidance related to blood and tissue donations and use of such products when impacted by a pandemic. The team also works with outside groups to address any blood shortages that might arise.

D.2.1.3 Medical Device Group

The Medical Device Group would manage issues related to an influenza pandemic operational response. Potential units, with team leaders from CDRH staff members, that may be needed to manage mitigation and recovery issues are the IVD Team, PPE and Other Devices Team, and Shortage Team.

D.2.1.3.1 In-Vitro Diagnostics Team

The IVD Team performs the following:

- Respond to triage EUA requests.
- Respond to inquiries regarding EUA requests from:
 - The CDC, U.S. military, and domestic and international commercial sources for IVDs claiming to subtype or detect the novel viral strain or to detect virus mutant variants.
 - Manufacturers regarding instruments to be used in the development of IVDs.
- Clear tests and instruments for the availability of detection of the novel influenza, including rapid tests and other influenza testing-related products, such as viral transport media/swabs.
- Monitor reagent and system shortages on a short-term (daily or weekly) basis as well as a long-term (monthly) basis.
- Monitor claims for detection and differentiation of the influenza virus.
- Review data and labeling of cleared or approved devices for which a company proposes new claims and changes.
- Work with the CDC to monitor availability of new influenza subtype panels from CDC/American Type Culture Collection (ATCC) for use by assay developers.
- Conduct rapid review of any promising influenza devices capable of differentiating novel subtypes, particularly those that are rapid or point-of-care tests, and those for detection of mutant variants of the virus.
- Address fraudulent claims by monitoring websites and complaints regarding claims to diagnose novel influenza and issuing warning letters as appropriate.
- Support the development of laboratory-developed tests for virus diagnosis.

D.2.1.3.2 Personal Protective Equipment and Other Devices Team

The PPE and Other Devices Team performs the following:

- Exchange information with CDC/SNS, States, and manufacturing sector and provide real-time monitoring of consumption/utilization rates of PPE during emergencies.
- Respond to State and private sector inquiries about perceived shortages during public health emergencies.



- Anticipate and plan for future surges in demand for N95 devices.
- Track and trace status of N95 devices released from SNS.
- Meet with manufactures about the development of new PPEs.
- Address shortages of PPE by working with industry to update current manufacturing capabilities and assist with long-term planning by the manufacturing sector to meet demands for a potential surge.

D.2.1.3.3 Shortage Team

The Shortage Team would be created if shortages of IVDs, PPEs, and other devices are too extensive to be managed by the above units alone.

D.2.2 Logistics Section

D.2.2.1 Employee Health Advisor

The Employee Health Advisor is a staff member of the OO Employee Safety and Environmental Management Staff (ESEMS) who addresses the need for appropriate health protection for high-risk FDA employees. The Employee Health Advisor works with HHS and the USPHS Federal Occupational Health (FOH) Services to ensure adequate medical countermeasures are made available to protect FDA responders.



E. COMMUNICATIONS AND INFORMATION MANAGEMENT

This section is reserved for text to be added at a future date.

F. AUTHORITIES AND REFERENCES

F.1 NATIONAL STRATEGIES

National Strategy for Pandemic Influenza

On November 1, 2005, President George W. Bush issued a *National Strategy for Pandemic Influenza* that called for comprehensive and coordinated pandemic preparedness planning at all levels of Government and the private sector. It outlines how the Nation intends to prepare, detect, and respond to a pandemic. This strategy describes the important roles to be played not only by the Federal Government, but also by State and local governments, private industry, international partners, and individual citizens. HHS was identified as the lead Department for medical response.

www.flu.gov/professional/federal/pandemic-influenza.pdf

National Strategy for Pandemic Influenza – Implementation Plan

In May 2006, the HSC published the *National Strategy for Pandemic Influenza – Implementation Plan*. The introductory letter signed by President George W. Bush cited more than 300 critical actions to address the threat of pandemic influenza. Chapter 6, *Protecting Human Health*, includes actions on (1) achieving national goals for producing and stockpiling vaccine and antiviral medications; and (2) prioritizing and distributing limited supplies of vaccine and antiviral medications. It details how the Nation is currently preparing for, and how it detects and responds to, a potential pandemic influenza outbreak. www.flu.gov/professional/federal/pandemic-influenza-implementation.pdf

F.2 FEDERAL PLANS AND GUIDANCE

HHS Pandemic Influenza Plan, Part 1 – Strategic Plan

The HHS Pandemic Influenza Plan, Part I – Strategic Plan (November 2005) contains a summary of major pandemic response roles for HHS officials, agencies, and divisions.

www.flu.gov/planning-preparedness/federal/hhspandemicinfluenzaplans.pdf

The major pandemic response roles for FDA include the following:

- Regulating manufacturing processes.
- Evaluating and licensing pandemic vaccines.
- Evaluating and approving antiviral drugs for influenza.
- Facilitating the development, evaluation, and clearance or approval of diagnostic tests and devices.
- Preparing reagents to standardize the potency of inactivated influenza vaccines.
- Preparing reference strains appropriate for vaccine manufacturing.
- Reviewing antiviral drug and pandemic vaccine supply issues.
- Evaluating and issuing EUAs when appropriate.
- Monitoring vaccine adverse events.
- Monitoring antiviral drug adverse events.
- Maintaining close communication with drug and vaccine manufacturers.
- Evaluating investigational new drug (IND) applications and investigational device exemptions (IDEs) for medical products that diagnose, treat, prevent, or mitigate influenza.

- Evaluating new manufacturing sites and processes for antiviral drugs.
- Making necessary changes in prescribing and patient information, including dosing, target populations, and other directions for use for antiviral drugs and pandemic vaccines based on research and adverse events.
- Evaluating long-term stability of stockpiled antiviral drugs for purposes of shelf-life extension.
- Monitoring to protect against the distribution of counterfeit antiviral drugs and pandemic vaccines.

HHS Pandemic Influenza Implementation Plan

The *HHS Pandemic Influenza Implementation Plan* (November 2006) provides a roadmap for the Department's pandemic preparedness and response. It outlines specific steps to implement the actions identified in the *HHS Pandemic Influenza Plan, Part 1 – Strategic Plan*.

www.flu.gov/planning-preparedness/federal/hhspandemicinfluenzaplan.pdf

F.3 FDA SUPPORTING DOCUMENTATION

FDA OPDIV Section to the HHS Pandemic Influenza Operational Plan

The FDA OPDIV section to the *HHS Pandemic Influenza Operational Plan* (November 21, 2006) includes essential functions that FDA Centers and Offices must continue to perform to ensure COOP in the event of an influenza pandemic.

Center/Office Emergency Plans and Procedures

The following plan supports implementation of this *Pandemic Influenza Annex to the FDA EOP*:

- *OC/OO/Office of Financial Operations (OFO)/OFM – Business Continuity Plan* (June 2013)



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Appendix A:

Protection of Workers: Guidance on Preparing the Workplace and Workers for an Influenza Pandemic

Introduction

An influenza pandemic occurrence will cause large numbers of employees to be absent from work because of illness, because they may have to care for ill family members, because schools or daycare centers are closed, or because they are afraid to come to work.

It is estimated that during a period of peak influenza pandemic illness, approximately 30 to 40 percent of employees working in a particular office or organization could be absent. An outbreak in a particular geographic area could last from 6 to 8 weeks. There is little way of knowing when an influenza pandemic will occur or how severe it will be in the population.

Planning for an influenza pandemic should assume a worst-case scenario that would be characterized by a high level of illness and absenteeism, social disruption, and economic loss in the public, private, and nonprofit sectors of the economy. The level of risk experienced by employees in the various FDA Centers and Offices will depend on the nature of their occupations and the degree to which they have occupational exposure to people potentially infected with the pandemic influenza virus.

Action Steps

Expanding teleworking by employees and “social distancing” are two actions that can be taken by managers to facilitate continuation of an agency’s essential functions despite high workforce absenteeism. Social distancing refers to employee behavior to reduce the frequency, proximity, and duration of contact between people (both employees and customers) to reduce the chances of spreading influenza from person-to-person.

Spread of Influenza

It is important that employees understand how influenza can be spread among people. It is spread primarily through large droplets (droplet transmission) that directly contact the nose, mouth, or eyes. Droplets are produced when infected people cough, sneeze, or talk. This sends relatively large infectious droplets and very small sprays (aerosols) into the nearby air and into contact with other people. The large droplets can only travel around 6 feet. Consequently, people should limit close contact with others to a distance no closer than 6 feet. A second way that influenza is transmitted is by individuals touching objects that have been contaminated with influenza viruses and then transferring the infected material from their hands to their nose, mouth, or eyes. A third way of transmitting influenza is through the spread of very small infectious particles (aerosols) that travel in the air. Employees need to understand these three principal means of transmission of influenza so that they can take steps, to the maximum extent possible, to protect themselves against infection.

Occupational Safety and Health Administration Guidance

The U.S. Department of Labor (DOL) Occupational Safety and Health Administration (OSHA) has issued a document entitled *Guidance on Preparing Workplaces for an Influenza Pandemic* (OSHA 3327-02N 2007 and updated version 3327-05R 2009), which provides detailed, but strictly advisory, guidance for employers on preparing their workplaces to minimize the impact of an influenza pandemic on their workers and operations. This guidance will help employers and employees identify the pandemic influenza risk levels in their individual workplace settings. OSHA identifies appropriate control measures for pandemic influenza—these measures include good hygiene, cough etiquette, social distancing, the use of PPE, and staying home from work when ill.

Although the work of the FDA Centers and Offices differs from other USG agencies and among themselves, there are many pandemic preparedness recommendations in the OSHA guidance publication that are applicable to all FDA elements. They include:

- Be aware of and review other USG, State, and local health department pandemic influenza plans; incorporate appropriate actions from these plans into workplace disaster plans.
- Prepare and plan for operations with a reduced workforce.
- Work with your suppliers to ensure you can continue to operate and provide services.
- Develop a sick leave policy that does not penalize sick employees, thereby encouraging employees who have influenza-related symptoms to stay home so they do not infect other employees; recognize that employees with ill family members may need to stay home to care for them.
- Identify possible exposure and health risks to your employees: Are your employees expected to have a lot of contact with the general public?
- Minimize exposure to fellow employees or the public.
- Identify business-essential functions and people required to sustain business-necessary functions and operations; prepare to cross-train or develop ways to function in the absence of these positions. It is recommended that employers train three or more employees to be able to sustain business-necessary functions and operations.
- Plan for downsizing services, but also anticipate any scenario that may require a surge in your services.
- Some employees will have individual risk factors that should be considered by employers as they plan how the organization will respond to a potential pandemic (e.g., immuno-compromised individuals and pregnant women).
- Stockpile items such as soap, tissue, hand sanitizer, cleaning supplies, and recommended PPE. When stockpiling items, be aware of each product's shelf-life and storage conditions, and incorporate product rotation into your stockpile management program (*Guidance on Preparing Workplaces for an Influenza Pandemic*, pp.13-15).

OSHA's *Guidance on Preparing Workplaces for Pandemic Influenza* notes that the two most effective ways of protecting employees from pandemic influenza depend upon emphasizing proper hygiene (i.e., disinfecting hands and surfaces) and practicing social distancing as previously described. OSHA describes a "hierarchy of controls" as the most effective way of dealing with a workplace hazard. This concept places a high priority on intervention strategies by management and on attempts to remove the hazard from the workplace rather than to rely primarily on the employees to reduce their exposure. Depending on the nature of the work of each FDA Center and Office, the strategies for work practice and engineering controls, administrative controls, work practices, and PPE will differ in both cost and effectiveness.

CDC Guidance

The CDC has issued a document entitled *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Nonpharmaceutical Interventions*, which provides interim planning guidance for State, local, tribal, and territorial communities. This planning focuses on several measures other than vaccination and drug treatment that might be useful during an influenza pandemic to reduce its harm. This interim guidance introduces a Pandemic Severity Index to characterize the severity of a pandemic, provides planning

recommendations for specific interventions that communities may use for a given level of pandemic severity, and suggests when these measures should be started and how long they should be used.

The pandemic mitigation interventions described in the *Interim Guidance* document include:

- **Isolation and Treatment.** Isolation may occur in the home or healthcare setting, depending on the severity of an individual's illness and/or current capacity of the healthcare infrastructure.
- **Home Quarantine.** Households should voluntarily quarantine members in these households with confirmed or probable influenza case(s) and consider combining this intervention with prophylactic use of antiviral medications, provided sufficient quantities of effective medications exist and that a feasible means of distributing them is in place.
- **Dismissal of Students from School.** Reductions of out-of-school social contacts and community mixing should occur.
- **Social Distancing.** Individuals should take social distancing measures to reduce contact between adults in the community and workplace, including cancellation of large public gatherings and alternation of workplace environments and schedules to decrease social density and preserve a healthy workplace to the greatest extent possible without disrupting essential services.
- **Individual Infection Control Measures.** Community-based strategies should be used in combination with individual measures, such as handwashing and cough etiquette.

The CDC also has available the *H1N1 Flu: A Guide for Community and Faith-Based Organizations* developed in response to H1N1 (www.flu.gov/planning-preparedness/community/cfbguidance.pdf).

Hierarchy of Controls

OSHA defines work practice controls as “procedures for safe and proper work that are used to reduce the duration, frequency, or intensity of exposure to a hazard.” Managers and supervisors should solicit suggestions from employees on ways to implement safe work practice controls. Engineering controls are preferred over all others because “they make permanent changes to reduce exposure to hazards and do not rely on employee or customer behavior.” These types of controls involve making permanent changes to the work environment to reduce work-related hazards.

Administrative controls include “controlling employees’ exposure by scheduling their work tasks in ways that minimize their exposure levels.” Examples of administrative controls include discontinuation of non-essential travel to locations with high illness transmission rates, implementing work practices such as email, websites, and teleconferences that minimize face-to-face contact between employees, and adopting flexible work arrangements, such as telecommuting or flexible work hours, to reduce the number of employees who must be at work at one time or in one specific location.

PPE is considered appropriate for employees during certain types of exposures, but is no replacement for other types of prevention interventions, such as engineering controls, cough etiquette, and hand hygiene. Examples of the types of PPE appropriate for a pandemic influenza include: gloves, goggles, face shields, and respiratory protection devices.

Each of the above types of work practices and controls may be appropriate for implementing in FDA Centers and Offices. However, there is no single list of these four prevention strategies that would necessarily be appropriate for implementing in each FDA organization. Rather, it is incumbent upon the director of each Center and Office to engage the employees and supervisors in their unit to examine how the work of their organization can be modified to provide maximum protection for the staff should an influenza pandemic occur.

All actions taken by FDA managers and supervisors must be consistent with and not conflict with other Federal, State, and local health department pandemic influenza plans. As appropriate, portions of these



other plans may be incorporated into individual pandemic influenza plans developed for individual FDA Centers and Offices.

HHS, Office of Personal Management (OPM), and U.S. General Services Administration (GSA) have documents and websites that provide policy and guidance applicable for emergency situations, such as an influenza pandemic. Human capital management, leave, temporary closing of work spaces and treatment of absences, and telework are all functions that may need to be implemented during the course of an influenza pandemic that may impact FDA Centers and Offices. As needed, directors and supervisors should consult the following documents/websites:

- OPM and GSA Policy on Telework
www.telework.gov
- HHS Telecommuting Program Policy
<http://intranet.hhs.gov/ohr/telework/policy.html>
- *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Nonpharmaceutical Interventions*
www.flu.gov/planning-preparedness/community/mitigation.html#